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UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WASHINGTON

UNITED STATES OF AMERICA,

Plaintiff,

v.

SAMI ANWAR,
MID COLUMBIA RESEARCH, LLC,
and ZAIN RESEARCH, LLC,

Defendants.

4:18-CR-6054-EFS

SUPERSEDING INDICTMENT

Vio: 18 U.S.C. § 1349
Conspiracy to Commit
Wire Fraud (Count 1)

18 U.S.C. § 1349
Conspiracy to Commit
Mail Fraud (Count 2)

18 U.S.C. § 1343
Wire Fraud
(Counts 3-25)

18 U.S.C. § 1341
Mail Fraud
(Counts 26-40)

21 U.S.C. § 843(a)(3)
Fraudulently Obtaining
Controlled Substances
(Counts 41-46)

21 U.S.C. § 843(a)(4)(A)
Furnishing False or
Fraudulent Material
Information
(Count 47)

18 U.S.C. § 981(a)(1)(C),
28 U.S.C. § 2461(c)
Forfeiture Allegations

The Grand Jury charges:

GENERAL ALLEGATIONS

At all times relevant to this Superseding Indictment:

Overview of the Conspiracy

1. Beginning at a date unknown, but no later than on or about November 25, 2013 the Defendants, SAMI ANWAR, and his companies, Mid Columbia Research LLC ("MID COLUMBIA RESEARCH"), and Zain Research LLC ("ZAIN RESEARCH"), together with other conspirators both known and unknown to the Grand Jury, devised, perpetrated, and carried out a scheme and artifice designed to enrich themselves financially by falsifying research data for human clinical trials, including a clinical trial for a medical study designed to prevent and lower opioid use and addiction.

2. Defendants' fraudulent scheme included forging and falsifying hundreds of documents to make it appear as though the study was being performed and supervised by a qualified and licensed medical physician; falsifying medical records and data to admit dozens of ineligible subjects into the study, including subjects who were employees of Defendants and family members of Defendants'

employees; falsifying research data including, but not limited to: electrocardiograms ("ECGs"), blood pressure and other vital signs, urinalysis results, visit and progress notes, and blood specimens drawn from employees of SAMI ANWAR and stolen from unwitting medical patients who were not part of the study; disposing of study medication designated for research subjects by shooting it down the drain, and then falsely recording that it had been injected as required; dangerously hoarding, in attics and desk drawers, opioids intended to be dispensed to study subjects as rescue medication in order to avoid detection, and then falsely recording that they had been dispensed as required; and fabricating diary entries required to be completed by study subjects in order to perpetrate and hide the fraud.

3. In this manner, and as described further herein, Defendants fraudulently sought over a half-million dollars, and fraudulently obtained, at the very least, more than a quarter-million dollars which was designated for legitimate medical research intended to help opioid addicts and to be relied upon as part of the drug approval process regulated by the United States Food and Drug Administration ("FDA") before Defendants' fraudulent scheme was uncovered.

FDA and DEA Regulation of Controlled Substances and Clinical Research Trials

4. Drug developers, or "sponsors," perform and oversee clinical research trials or "investigations" to gather data regarding how new drug treatments impact human subjects. Clinical trials are research studies conducted on voluntary human subjects that are designed to answer specific questions about the safety or effectiveness of drugs, vaccines, other therapies, or new ways of using existing treatments.

5. The FDA is responsible for ensuring that drugs intended for human use are safe and effective. FDA relies on the results of clinical trials funded and

conducted by sponsors to make regulatory decisions regarding the approval of drugs.

6. Drug sponsors sometimes contract with contract research organizations ("CROs") (sometimes also known as a clinical research organization) in order to oversee and conduct clinical research trials. Per federal regulations (21 C.F.R. § 312.3), a CRO assumes, as an independent contractor with the sponsor, one or more of the obligations of a sponsor's obligations in carrying out a clinical trial.

7. CROs and Sponsors often contract with multiple research sites to perform clinical trials. Under such an arrangement, each individual research site is responsible for identifying subjects, entering them into the study, performing the study, gathering data, and reporting the data to the Sponsor and/or CRO, all in accordance with protocol and clinical trial agreements entered into among the Sponsor, CRO, and the individual research site.

8. A "principal investigator," "clinical investigator," or "investigator" is the individual responsible for conducting a clinical investigation, including overseeing the selection and qualification of subjects, the dispensation of the study drug, the collection and reporting of data, and the other aspects of the investigation. Under FDA regulations, an investigator is responsible for ensuring that an investigation is conducted according to the signed investigator statement, the investigational plan (known as a "protocol"), and applicable regulations; for protecting the rights, safety, and welfare of subjects under the investigator's care; for obtaining the informed consent of each research subject who participates in the investigation; and for ensuring that drugs and controlled substances used in the investigation are appropriately maintained, stored, dispensed, and accounted for.

9. Though the FDA approves drugs for medical use in the United States, the Drug Enforcement Administration ("DEA") regulates the handling of all controlled substances, including those being used by researchers to conduct clinical research. Therefore, a Sponsor, CRO, or research site seeking to conduct an investigation using controlled substances regulated under the Controlled Substances Act must order, possess, store, distribute, and administer the controlled substance pursuant to a valid registration issued by the DEA and applicable regulations. These regulations require, for those drugs designated by the DEA as Schedule I or Schedule II controlled substances, that any such controlled substance be ordered by an approved registrant or registered power of attorney on an official order form signed by the registrant (known as a form DEA-222), that the registrant keep detailed and accurate records for inventory of such substances, and that such substances be stored in locked containers complying with DEA regulations. Moreover, in order to conduct a research study using a Schedule I controlled substance, an entity must seek and obtain approval from the DEA.

The Defendants and Certain Identified Co-Conspirators

10. The Conspiracy involved numerous conspirators, both individuals and entities, known and unknown to the Grand Jury. In addition to the named Defendants, the conspirators included employees of SAMI ANWAR, MID COLUMBIA RESEARCH, ZAIN RESEARCH, other companies owned and controlled by SAMI ANWAR, including a company identified herein as "Company A", and certain of the subjects purportedly participating in the trials. SAMI ANWAR directed all of the acts undertaken in furtherance of the conspiracy.

11. SAMI ANWAR was a resident of the Eastern District of Washington who was the owner, operator, and sole governor of MID COLUMBIA

RESEARCH and ZAIN RESEARCH, and the owner, operator, and one of the two governors of Company A. SAMI ANWAR was responsible for all operations of MID COLUMBIA RESEARCH and ZAIN RESEARCH, and also those of Company A. At no time relevant to this Superseding Indictment was SAMI ANWAR ever licensed to practice medicine in the United States.

12. Between at least July 6, 2017 and the present, Defendant MID COLUMBIA RESEARCH was a Washington State for-profit, limited liability corporation and research site with its place of business in Richland, Washington. MID COLUMBIA RESEARCH was owned, operated, and governed by SAMI ANWAR, and held itself out as conducting clinical trials for sponsors and CROs. MID COLUMBIA RESEARCH's employees and operations were controlled and directed by SAMI ANWAR. During the entire course of the Conspiracy, beginning at least on or about July 20, 2016, SAMI ANWAR used MID COLUMBIA RESEARCH's name, and close derivations thereof, on applications to CROs, sponsors, and the Drug Enforcement Administration.

13. At all times relevant to this Superseding Indictment, Defendant ZAIN RESEARCH was a Washington State for-profit, limited liability corporation and research laboratory with its place of business in Richland, Washington. ZAIN REASEARCH was founded in February 2013 and, at all relevant times, was owned, operated, and governed by SAMI ANWAR. ZAIN RESEARCH held itself out as conducting clinical trials for sponsors and CROs. ZAIN RESEARCH's employees and operations were controlled and directed by SAMI ANWAR.

14. At all times relevant to this Superseding Indictment, Company A was a Washington State non-profit corporation and medical facility with its place of business in Richland, Washington. Company A was owned, operated and governed by SAMI ANWAR. SAMI ANWAR's wife was also a governor of

Company A at times relevant to the Superseding Indictment. Company A, through its healthcare practitioners and staff, held itself out as providing healthcare services to patients. Company A's employees and operations were controlled and directed by SAMI ANWAR.

15. Company A, ZAIN RESEARCH, and MID COLUMBIA RESEARCH were co-located within the same building, and also shared certain employees and a drug dispensary. Company A provided healthcare services to patients, while ZAIN RESEARCH and, later, MID COLUMBIA RESEARCH, purportedly conducted clinical trials on human subjects on behalf of Sponsors and CROs. Company A employed a licensed physician, known to the Grand Jury and referred to herein by the pseudonym "Dr. Doe." As part of the Conspiracy, because SAMI ANWAR was not a licensed physician, he would falsely represent to sponsors and CROs that Dr. Doe as a licensed physician was the principal investigator for studies of which Dr. Doe had no knowledge and in which Dr. Doe had no participation as required for a principal investigator.

16. ZAIN RESEARCH and MID COLUMBIA RESEARCH generally maintained a "subject binder" for each research subject of each clinical trial. These subject binders included, but were not limited to, documents such as: (1) records documenting the screening or intake process determining whether or not the subject was eligible including, for many studies, medical histories and records reflecting the appropriate diagnoses or conditions; (2) records documenting the subject's informed consent to participating in the study; (3) records documenting the subject's relevant vital signs and other data at the time of admission to the study; (4) records documenting each visit for the subject, including the date and time of the visit and progress notes describing the visit, any concerns or adverse events reported by the subject, and the relevant vital signs and other data at the

time of each visit; (5) records documenting the dispensation of the study drug at each visit; (6) records documenting the dispensation of any rescue medication dispensed, that is, any medication provided to the subject to take, as needed, between visits, and whether any rescue medication was taken or returned by the subject from the prior visit; and (7) subject diaries documenting the subject's subjective experience while on the study, including, as applicable, pain experienced by the subject, the time and date, and whether the subject took rescue medication to relieve any pain experienced.

17. ZAIN RESEARCH and MID COLUMBIA RESEARCH employed various individuals, including: regulatory managers, who were responsible for interacting with Sponsors, CROs, and regulatory agencies; study coordinators, who were responsible for interacting with research subjects in carrying out the study and completing and assembling subject binders; research technicians, who were responsible for conducting blood pressure readings, electrocardiograms (ECGs), drawing blood from subjects, and reporting test results; administrative staff, who were responsible for scheduling subject visits and ensuring that subjects were paid for each visit; drug dispensary staff, who were responsible for ensuring that ZAIN RESEARCH and MID COLUMBIA RESEARCH maintained adequate records demonstrating the dispensation and inventory of each study drug and controlled substance; and others.

18. Company A maintained electronic medical records for each of its patients. Company A employed physicians and other healthcare practitioners, medical assistants, and billing personnel. Other than SAMI ANWAR and certain other high-level management personnel, Company A personnel, including physicians, typically had no involvement regarding the clinical trials being conducted by the Defendants.

19. Between February 2013 and November 2018, the Defendants conducted various clinical trials on behalf of sponsors and CROs located throughout the United States.

The Pfizer Cholesterol Study

20. Pfizer, Inc. ("Pfizer") is a Sponsor and multinational pharmaceutical company which has its headquarters in New York City, New York and its research headquarters in Groton, Connecticut. Pfizer develops, manufactures, markets, and sells pharmaceutical products.

21. In or about 2013, Pfizer sponsored a study (Protocol #B1481020) of an experimental drug for individuals with high cholesterol who were at risk of cardiovascular events (the "Cholesterol Study").

22. Pfizer contracted with a CRO known as ICON Clinical Research, Inc. (ICON), a Pennsylvania Corporation with a place of business in North Wales, Pennsylvania, to conduct and provide day-to-day oversight over the Cholesterol Study.

23. ICON, acting on behalf of Pfizer, contracted with numerous independent research sites, including ZAIN RESEARCH, to conduct the Cholesterol Study at individual site locations.

24. On November 25, 2013, ICON, acting on behalf of Pfizer, and ZAIN RESEARCH entered into a Clinical Trial Agreement to conduct the Cholesterol Study. While SAMI ANWAR conducted all negotiations with ICON and Pfizer and signed the Clinical Trial Agreement on behalf of ZAIN RESEARCH, SAMI ANWAR was not and is not a licensed physician in the United States, and the clinical investigator on the Cholesterol Study, like other studies, was required to be a licensed physician. Accordingly, SAMI ANWAR set forth a licensed physician, referred to herein as "Dr. N," as the principal investigator.

25. Study data for the Cholesterol Study, including, but not limited to, data regarding each subject purportedly enrolled in the study and participating in the study, was uploaded by ZAIN RESEARCH to InForm, an internet-hosted electronic data capture ("EDC") system, where it was transmitted by interstate wires to, and viewed by, ICON and Pfizer employees and agents located in various states, including, without limitation, Pennsylvania, the location of ICON's U.S. Headquarters.

26. ICON was responsible for making all payments to ZAIN RESEARCH for the Cholesterol Study, using funds that had been provided by Pfizer for that purpose. ICON personnel located in Pennsylvania reviewed the data submitted by ZAIN RESEARCH into InForm and made payment to ZAIN RESEARCH based on and, relying upon, the data entered by ZAIN RESEARCH regarding the number of eligible subjects enrolled into the trial and the number of subject visits purportedly performed by ZAIN RESEARCH in accordance with the protocols of the trial. ZAIN RESEARCH was entitled to receive payment only for those subjects properly enrolled into the trial under the supervision of the principal investigator, a licensed physician, only for those subjects who were eligible to participate in the trial in accordance with the inclusion and exclusion criteria set forth in the protocol, and only for those subject visits that actually occurred under a licensed physician's supervision and were conducted in accordance with the protocol's requirements. Based on the per-subject, per-visit InForm data uploaded and transmitted by ZAIN RESEARCH through interstate wires to ICON, ICON issued a check to ZAIN RESEARCH and mailed it, via the United States Postal Service, from ICON's United States headquarters located in North Wales, Pennsylvania, to ZAIN RESEARCH's Richland, Washington facility. In this

manner, ZAIN RESEARCH and SAMI ANWAR received at least $136,871.09 from ICON and Pfizer for the Cholesterol Study.

27. With regard to the use of the investigational drug for the Cholesterol Study, bococizumab, ZAIN RESEARCH was responsible for electronically entering data into an interactive response technology ("IRT") system, concerning the number of investigational doses provided to eligible subjects purportedly enrolled into the study. The data entered into the IRT system at ZAIN RESEARCH's Richland, Washington facility was transferred, via interstate wires, to Pfizer's systems, employees, and agents located in various states, including, but not limited to, Pfizer's servers in New Jersey. Based on the IRT data entered by ZAIN RESEARCH, Pfizer was responsible for supplying the investigational drug. Pfizer did so by causing Fisher Clinical Services ("Fisher"), a pharmaceutical distributor headquartered in Allentown, Pennsylvania, to ship the investigational drug via a commercial interstate carrier from Fisher's Allentown, Pennsylvania location to ZAIN RESEARCH's Richland, Washington facility.

The Pfizer Smoking Cessation Study

28. In 2013, Pfizer was also conducting a study (Protocol A3051073) involving an experimental drug to assist adolescent smokers in their efforts to quit smoking (the "Smoking Cessation Study"). Pfizer contracted with Parexel International ("Parexel"), a CRO with its headquarters in Waltham, Massachusetts, to conduct and perform day-to-day oversight of the Smoking Cessation Study. Parexel and Pfizer then contracted with individual site laboratories, including ZAIN RESEARCH, to conduct the Smoking Cessation Study.

29. As with the Cholesterol Study, Dr. N was designated as the principal investigator for ZAIN RESEARCH for the Smoking Cessation Study. ZAIN

RESEARCH's work on the Smoking Cessation Study began no later than on or about November 26, 2013.

30. Study data for the Smoking Cessation Study, including, but not limited to, data regarding each subject purportedly enrolled in the study and participating in the study, was uploaded by ZAIN RESEARCH to an EDC system, where it was transmitted by interstate wires to, and viewed by, Parexel and Pfizer employees and agents located in various states, including, without limitation, Massachusetts, Parexel's principal place of business.

31. With regard to the use of the investigational drug for the Smoking Cessation Study, varenicline, ZAIN RESEARCH was responsible for electronically entering data into an interactive response technology ("IRT") system, concerning the number of investigational doses provided to eligible subjects purportedly enrolled into the study. Based on the IRT data entered by ZAIN RESEARCH, Pfizer was responsible for supplying the investigational drug. Pfizer did so by causing a commercial interstate carrier to ship the investigational drug to ZAIN RESEARCH's Richland, Washington facility.

32. The Cholesterol Study and Smoking Cessation Study were only two of the studies conducted by ZAIN RESEARCH between February 2013 and July 2016. Between February 2013 and July 2016, ZAIN RESEARCH and SAMI ANWAR conducted numerous other studies with Dr. N identified as the principal investigator. Other studies purportedly conducted by ZAIN RESEARCH and SAMI ANWAR during this time period for which Dr. N was designated as principal investigator included trials concerning asthma, diabetes, alzheimer's, multiple sclerosis, liver cirrhosis, scabies, and many more.

The Braeburn Study

33. Braeburn Pharmaceuticals, Inc. ("Braeburn"), which has its principal place of business in Princeton, New Jersey, is a Sponsor and pharmaceutical company that develops drugs to combat the opioid addiction epidemic. During the time period relevant to this Superseding Indictment, Braeburn sponsored a study for an investigational drug known as CAM 2038. CAM 2038 is an investigational product intended to treat moderate to severe opioid addiction through periodic injections of slow-releasing buprenorphine. During the time period relevant to this Superseding Indictment, Braeburn sponsored clinical trials of CAM 2038 in order to gather data for FDA to use in making regulatory decisions regarding CAM 2038 and its potential efficacy and safety in treating opioid use and addiction.

34. Braeburn contracted with Medpace, Inc. ("Medpace"), a CRO which has its principal place of business in Cincinnati, Ohio, to conduct and provide day-to-day oversight of the CAM 2038 Study. Medpace, in turn, contracted with numerous independent research sites, including MID COLUMBIA RESEARCH, to conduct CAM 2038 studies at individual research site locations.

35. On July 20, 2016, SAMI ANWAR submitted a "Pain Clinical Trial Questionnaire" to Medpace and Braeburn setting forth its intent to participate as an individual research site as part of the CAM 2038 Study. The Questionnaire submitted by SAMI ANWAR falsely stated that it was prepared by a physician employed by Company A, known to the Grand Jury and referred to herein as "Dr. Doe," and that Dr. Doe was the intended clinical investigator. SAMI ANWAR's personal cellular phone number was listed as the "primary phone number," and "Dr." SAMI ANWAR was listed as the primary contact.

36. On or about November 8, 2016, SAMI ANWAR entered into a Clinical Trial Agreement with Medpace, with Braeburn as the intended third-party

beneficiary, to perform a study regarding CAM 2038 (referred to herein as "the CAM 2038 Study" or "the Braeburn Study"). While SAMI ANWAR conducted all negotiations with Medpace and Braeburn, SAMI ANWAR is not a licensed physician in the United States, and the clinical investigator on the CAM 2038 study, like other studies, was required to be a licensed physician. Accordingly, SAMI ANWAR set forth Dr. Doe as the clinical investigator. SAMI ANWAR forged Dr. Doe's signature on the Clinical Trial Agreement between Medpace and "Mid-Columbia Research."

37. Pursuant to the Clinical Trial Agreement, Medpace and Braeburn paid MID COLUMBIA RESEARCH on a per-subject, per-visit basis. That is, MID COLUMBIA RESEARCH was eligible for payment only for subjects who were properly and legitimately enrolled in the study based on the eligibility criteria set forth in the study protocol (hereinafter referred to as "the protocol"), and only for those visits in which the subject actually participated. The Clinical Trial Agreement designated MID COLUMBIA RESEARCH, Attention: SAMI ANWAR, as the payee. As payment agent and CRO, Medpace was responsible to make payment to MID COLUMBIA RESEARCH, using Braeburn funds that Medpace administered on Braeburn's behalf. In order to obtain payment, Defendants, and their known and unknown co-conspirators, submitted study data and per-subject, per-visit information electronically to Medpace, using the interstate wires. Specifically, the Defendants, and their known and unknown conspirators, electronically entered, in Richland Washington, the study data and per-subject, per-visit information into Medpace's electronic data capture (EDC) system, known as ClinTrak and electronically submitted it to Medpace, where it was delivered to, and received by, Medpace on Medpace's servers and electronic systems located in Cincinnati, Ohio. Based on the study data and per-subject, per-

visit information entered and submitted by Defendants, Medpace calculated the amounts to be paid to MID COLUMBIA RESEARCH. Medpace then paid MID COLUMBIA RESEARCH, using funds that had been provided by Braeburn for the study, by drawing checks on the Braeburn-provided funds and mailing them, through the United States Postal Service and Federal Express, a private interstate commercial carrier, to MID COLUMBIA RESEARCH, to SAMI ANWAR's attention.

38. In this manner, and as described further herein, Defendants, through the Conspiracy, obtained $274,642.80, from Braeburn through Medpace, which was deposited into a business banking account controlled by SAMI ANWAR (account number xxxx7574). At times relevant to this Superseding Indictment and after receipt of the payments from Braeburn through Medpace, at least $175,000.00 was transferred from that business account into a personal bank account of SAMI ANWAR.

39. In order to gain approval for the study, MID COLUMBIA RESEARCH was also required to submit a completed form FDA-1572, Statement of Investigator, by a licensed and registered physician to act as the clinical investigator for the study. SAMI ANWAR forged Dr. Doe's signature on the FDA-1572 form submitted to Braeburn and Medpace for the Braeburn study. The FDA-1572 form falsely represented to Braeburn and Medpace that the clinical investigator, Dr. Doe, would "personally conduct or supervise" the investigation, would "maintain adequate and accurate records," would comply with FDA regulations and requirements regarding clinical investigator responsibilities, and would conduct the study in accordance with the "relevant, current protocol."

40. In accordance with the Braeburn study protocol and clinical trial agreement, Braeburn provided the "study drug," that is, the CAM 2038

buprenorphine shots that were the subject of the investigation. Buprenorphine is a Schedule III Controlled Substance. MID COLUMBIA RESEARCH was required to purchase and supply the "rescue medication," the morphine and hydrocodone that was dispensed to study subjects to take as needed between visits. Study subjects were required to document any rescue medication that they took between CAM 2038 shots, and were required to document the time of day, date, and level of pain that the subjects were in at the time of taking any rescue medication.

41. Both types of rescue medication, used in the Braeburn study, morphine and hydrocodone, are Schedule II controlled substances. Hydrocodone is a semi-synthetic opioid synthesized from codeine. It is a narcotic analgesic. Hydrocodone can be combined with acetaminophen, a non-narcotic pain reliever. Morphine is an opioid pain reliever that is naturally occurring in certain plants. Morphine is a narcotic analgesic that can be taken orally or injected intravenously or subcutaneously.

42. Schedule II controlled substances such as morphine and hydrocodone must be ordered through use of a DEA form known as a DEA-222. To obtain a Schedule II controlled substance such as morphine or hydrocodone, the practitioner must not only be a licensed healthcare practitioner, but must be registered with the DEA to provide Schedule II controlled substances. The rescue medication for the Braeburn study was supplied by a company known as Clinical Supplies Management, Inc. ("CSM") a clinical supply company with its principal place of business in Fargo, North Dakota. MID COLUMBIA RESEARCH ordered the rescue medication for the Braeburn study by submitting completed and signed DEA-222 forms to CSM in Fargo, North Dakota. CSM then filled the order and mailed the package, via United Parcel Service ("UPS"), a private interstate commercial carrier, containing the rescue medication to MID COLUMBIA

RESEARCH's Richland, Washington facility. SAMI ANWAR used Dr. Doe's DEA registration number and forged Dr. Doe's signature on each of the DEA-222 forms that ordered hydrocodone and morphine for the Braeburn study.

The GHB Study

43. Gamma Hydroxybutyrate ("GHB") is a central nervous system depressant that is a Schedule I Controlled Substance, the most tightly-controlled type of controlled substance. GHB is commonly known as the "date rape" drug because it is colorless and odorless and because of its ability to incapacitate victims who ingest it unknowingly and to leave victims with little or no memory afterward. In order to be classified as a Schedule I Controlled Substance, a drug must have no currently accepted medical use in treatment in the United States. In order to perform clinical trials using a Schedule I Controlled Substance such as GHB, an applicant must receive special authorization from the DEA.

44. Flamel Technologies ("Flamel") is part of Avadel Pharmaceuticals plc, a pharmaceutical company headquartered in Dublin, Ireland and with its United States headquarters located in Chesterfield, Missouri. In 2016, the FDA permitted Flamel to proceed with a study involving the use of a form of GHB on subjects suffering from narcolepsy, a sleep disorder (the "GHB Study"). Flamel contracted with INC Research, a CRO located in Raleigh, North Carolina, to conduct the GHB Study.

45. On or about May 12, 2017, MID COLUMBIA RESEARCH submitted an application to DEA to conduct the GHB Study. The application set forth Dr. Doe as the clinical investigator. As with the Clinical Trial Agreement, the FDA-1572 form, and numerous other documents concerning the Braeburn Study, SAMI ANWAR forged Dr. Doe's signature on the DEA application for the

GHB Study. Dr. Doe was not aware of the proposed GHB Study at the time of the application's submittal.

COUNT 1
CONSPIRACY TO COMMIT WIRE FRAUD

46. The Grand Jury re-alleges and incorporates by reference paragraphs 1 through 45 of the Superseding Indictment as if fully set forth herein. Further, the allegations in all other counts in the Superseding Indictment are re-alleged and incorporated into this count as if fully set forth herein.

47. Beginning on a date unknown to the Grand Jury, but no later than on or about November 25, 2013, and continuing until at least on or about November 16, 2018, in the Eastern District of Washington, Defendants SAMI ANWAR, MID COLUMBIA RESEARCH, ZAIN RESEARCH, and other persons and entities both known and unknown to the Grand Jury, did knowingly combine, conspire, and agree to commit certain offenses against the United States including the following offenses, referred to herein as the Conspiracy, to wit, knowingly devised and intended to devise a scheme and artifice to defraud Braeburn, Medpace, Pfizer, ICON, and Parexel, and other sponsors, CROs, and prospective sponsors and CROs, both known and unknown to the Grand Jury, and to obtain payments from Braeburn, Medpace, Pfizer, ICON, and Parexel, and other sponsors and prospective sponsors, both known and unknown to the Grand Jury, using signals and sounds transmitted by means of wire communication in interstate commerce to execute and attempt to execute the said scheme and artifice to defraud, in violation of 18 U.S.C. §§ 1343, 1349.

48. As part of the Conspiracy described herein, Defendants transmitted, and caused to be transmitted, by means of wire communication in interstate commerce, writings, signals, and sounds, from the Defendants' location in

Richland, Washington, to the various states, including, but not limited to, the Medpace electronic servers and systems located in Cincinnati, Ohio, Parexel's electronic systems and servers located in Waltham, Massachusetts, and ICON's electronic systems and servers located in North Wales, Pennsylvania, and to other interstate locations, in order to advance, further, and carry on the Conspiracy.

WAYS, MANNERS, AND MEANS OF THE CONSPIRACY

49. It was part of the Conspiracy that the Defendants, and their known and unknown co-conspirators, made numerous false and fraudulent statements and misrepresentations in order to fraudulently obtain approval to conduct multiple clinical research trials, to fraudulently obtain investigational drugs, including scheduled controlled substances, and to fraudulently seek and obtain payments from multiple sponsors and CROs for the fraudulently conducted clinical research trials.

50. It was further part of the Conspiracy that the Defendants, and their known and unknown co-conspirators attempted to silence, discredit, and intimidate individuals with direct knowledge of the Conspiracy in order to avoid detection by sponsors, CROs, government regulators, and law enforcement.

Defendants' Fraudulent Activity Between November 2013 and July 2016

51. Between at November 2013 and July 2016, SAMI ANWAR and ZAIN RESEARCH, and their known and unknown co-conspirators, perpetrated their fraudulent scheme on multiple clinical research trials with Dr. N listed as the primary investigator.

52. Dr. N's speciality is psychiatry and sleep medicine. While Dr. N was generally aware of some of the studies being conducted by ZAIN RESEARCH and SAMI ANWAR between November 2013 and July 2016, at SAMI ANWAR's direction, he was not personally conducting or supervising the study as required by

FDA regulations, the clinical trial agreements, and the applicable protocols. Rather, SAMI ANWAR personally directed and controlled all of ZAIN RESEARCH's research activities. While Dr. N occasionally saw research subjects and reviewed and signed certain study documentation between November 2013 and March 2015, SAMI ANWAR frequently refused to allow Dr. N to see research subjects or to review study documentation including research subject binders. As a result, not only were the studies not being conducted by a licensed physician and authorized principal investigator, as required by FDA regulations and the applicable clinical trial agreements and research protocols, but the patients who had enrolled in the research studies were not under the care and supervision of a licensed physician regarding their participation in the studies, significantly jeopardizing their health and safety.

53. Between November 2013 and March 2015, Dr. N's medical offices were co-located with ZAIN RESEARCH. During this time period, Dr. N occasionally saw research subjects and reviewed study documentation, although SAMI ANWAR was directing, conducting, and supervising all of ZAIN RESEARCH's activities. In March 2015, ZAIN RESEARCH moved to a new location, away from Dr. N's offices. From this point forward, SAMI ANWAR began conducting substantially all visits and forging all documents for Dr. N.

54. SAMI ANWAR regularly forged Dr. N's signature on study documentation, including, but not limited to: FDA-1572 forms (the FDA statement of investigator form certifying compliance with FDA requirements that is required for any investigator to participate in a study); resumes and curriculum vitae provided to sponsors in support of Dr. N's participation; verifications of subject eligibility to participate in the studies; screening checklists regarding subject eligibility; verification that the patient had provided informed consent for the study

after opportunity for consultation with a licensed physician; progress notes documenting purported subject visits and verifying that subjects were "fully compliant" with participation in the study, had experienced no adverse events, and were being monitored by a licensed physician for "safety and efficacy"; laboratory results for subjects participating in the study and purportedly verifying that the results were not "clinically significant"; worksheets documenting that a licensed physician had fully assessed the subject for depression, anxiety, and potential suicidal thoughts; and other documentation.

55. ZAIN RESEARCH employees, including, but not limited to J.C., L.D., H.E., and B.B., frequently observed SAMI ANWAR forging Dr. N's signature on these and other documents, and confronted him, but SAMI ANWAR continued to forge Dr. N's signature. For example, when one ZAIN RESEARCH employee, J.C., confronted SAMI ANWAR regarding the forgeries, SAMI ANWAR responded that he would not allow J.C. to move up in the company.

56. SAMI ANWAR and ZAIN RESEARCH used these forgeries to, deceive CRO and sponsor monitors and auditors into believing that Dr. N was conducting the studies, when in fact all activities were being controlled and directed by SAMI ANWAR. For example, in one instance, Dr. N confronted SAMI ANWAR regarding a forged signature on a study document, and SAMI ANWAR responded that it was necessary to forge Dr. N's signature because SAMI ANWAR needed to show the document to a monitor. When a Pfizer employee monitoring the Cholesterol Study noted that Dr. N's signature appeared different on different documents, SAMI ANWAR instructed employees, including B.B., that, going forward, SAMI ANWAR was to sign all documents for Dr. N, so that all the signatures would match. However, when CRO monitors on the Cholesterol

Study confronted SAMI ANWAR regarding the signatures, SAMI ANWAR admitted that sometimes he signed for Dr. N because he was "too busy."

57. SAMI ANWAR also frequently posed as Dr. N on the phone when monitors or sponsors needed to speak to the principal investigator. Moreover, SAMI ANWAR and ZAIN RESEARCH falsely provided SAMI ANWAR's cell phone number to Pfizer and ICON as Dr. N's number so that when Pfizer and ICON representatives attempted to get in contact with Dr. N, they would call SAMI ANWAR instead, and he could pose as Dr. N.

58. SAMI ANWAR and ZAIN RESEARCH frequently enrolled subjects that were not eligible to participate in the studies. These subjects frequently did not have the required medical conditions to participate, were not on the appropriate medication or medication doses, did not have appropriate medical records supporting their inclusion in the study, or otherwise were not eligible to participate. At SAMI ANWAR's explicit direction, these subjects were enrolled in the study whether or not they were eligible, and, at times, regardless of the risk to the subjects.

59. For example, in one study regarding diabetes, many of the subjects were not eligible to participate, but SAMI ANWAR directed that they nonetheless be admitted into the study. SAMI ANWAR directed ZAIN RESEARCH employees, including L.D., one of the study coordinators, that subjects who were already taking multiple other anti-diabetic medications be admitted to the study so that SAMI ANWAR and ZAIN RESEARCH could bill for those subjects. Because these subjects were already taking multiple other anti-diabetic medications, they were not eligible for the study, both because their use of other anti-diabetic medications meant that the study data could be corrupted and unreliable, and because the use of an experimental product concurrently with other

medication to treat the same condition could cause negative interactions that could potentially harm the subjects. L.D., the study coordinator responsible for this study was concerned that one of these subjects would die because SAMI ANWAR had enrolled them in the study while they were on other anti-diabetic medication, or that the data would be corrupted, leading to health problems down the road if sponsors or FDA relied on the fraudulent data.

60. As another example, on the same diabetes study, in or about December 2015 or January 2016, ZAIN RESEARCH staff determined that some of the patients were not eligible because they did not have the "biomarker" blood results necessary for inclusion into the study, SAMI ANWAR directed that ZAIN RESEARCH staff draw blood from other subjects in the study and that it be falsely identified as being from the ineligible subjects so that it would appear that they qualified and they could be enrolled in the study. Several ZAIN RESEARCH employees, including A.T., the lab technician and L.D., the study coordinator, refused to carry out SAMI ANWAR's direction to use falsely labeled blood in this manner; however, these subjects were still enrolled in the study.

61. SAMI ANWAR also directed that ZAIN RESEARCH admit ineligible subjects who fell under "exclusion criteria", rendering them ineligible to participate. These "exclusion criteria" are adopted by the sponsor because if a subject falls under an exclusion criteria, participation in the study would jeopardize either the integrity of the data or the health and safety of the subject, or both. If a subject fell under an "exclusion criteria," SAMI ANWAR directed that the study coordinator simply omit it from the documentation so that it would appear that the subject was eligible.

62. One automatic exclusion criteria from all of the studies was that the subject not be currently enrolled in any other study. As with other exclusion

criteria, this was necessary both in order to protect the integrity of the study data and to protect the health and safety of the patient. SAMI ANWAR and ZAIN RESEARCH frequently violated this criteria by enrolling the same subjects in multiple studies. For example, many of the subjects in the Cholesterol Study were also enrolled in other studies at the same time. SAMI ANWAR knew, and was concerned, that monitors and sponsors would learn of this clear violation of the study requirements. When one ZAIN RESEARCH employee, J.C., confronted SAMI ANWAR regarding having subjects enrolled in multiple studies simultaneously, SAMI ANWAR asked him "If a general goes out to battle, will the soldiers let him die?", meaning that SAMI ANWAR expected ZAIN RESEARCH employees to lie about and conceal this fraud in order to protect SAMI ANWAR.

63. In another instance, a particular subject, "W", was enrolled by SAMI ANWAR and ZAIN RESEARCH into multiple studies concurrently. W was not only enrolled in the Cholesterol Study, but also an Alzheimer's study being conducted by ZAIN RESEARCH, as well as a diabetes study. Not only was it in violation of the relevant protocols for W to be enrolled concurrently in multiple studies, but W had never been properly assessed by a licensed physician regarding the extent to which he was eligible to or could safely participate in any of the studies, let alone all of them at the same time. In March of 2015, W passed away from kidney disease, a common complication of diabetes. At SAMI ANWAR's direction, W's death was not reported to the study sponsors.

64. These are merely examples of SAMI ANWAR and ZAIN RESEARCH's fraudulent enrollment of ineligible research subjects. SAMI ANWAR consistently directed ZAIN RESEARCH staff, including J.C., B.B., and L.D., all study coordinators on various studies, to admit as many subjects as possible, without regard to whether those subjects were eligible to participate or

even whether they could safely participate in the study. SAMI ANWAR and ZAIN RESEARCH did this so that they could bill sponsors and CROs for these subjects, as ZAIN RESEARCH received payment on a per-subject, per-visit basis.

65. In addition to fraudulently enrolling subjects, ZAIN RESEARCH and SAMI ANWAR frequently falsified study data related to subject visits. When subjects did show up for their visits, they were typically seen by SAMI ANWAR, not Dr. N. SAMI ANWAR, who was not a licensed physician and not the principal investigator, was responsible for assessing their condition, performing any tests and exams, signing off on vital signs, lab reports, or progress notes, reporting any adverse actions experienced by the subjects or any changes in their medical conditions, and making the determination that they could safely continue to participate in the study. SAMI ANWAR would then forge Dr. N's signature on the study documents.

66. Many of the subjects enrolled in the studies frequently failed to show up for their weekly visits at all. For these subjects, SAMI ANWAR directed ZAIN RESEARCH employees to submit fraudulent data falsely stating that these subjects attended their visits. If a study subject failed to attend a weekly visit, SAMI ANWAR frequently directed ZAIN RESEARCH staff, including J.C., to falsely use the same vital signs and parameters from the previous visit, and falsely submit that information to the study sponsor and CRO. SAMI ANWAR and ZAIN RESEARCH did this so that they could continue billing sponsors and CROs for these subjects and for these false subject visits.

67. For example, in a study involving scabies, SAMI ANWAR and ZAIN RESEARCH enrolled approximately 100 subjects, of which few, if any, were legitimately participating in the study. The study protocol required that skin scrapings be taken at subject visits, but skin scrapings were not taken because the

subjects were not attending visits, did not have scabies, and/or were not legitimately participating in the study.

68. SAMI ANWAR and ZAIN RESEARCH further jeopardized patient and public health and safety by fraudulently failing to report adverse reactions in order to keep subjects enrolled in studies so that they could be billed. All studies require that subjects be asked to report, and that the laboratory report to the sponsor and CRO, any adverse reaction or significant adverse reaction experienced by the subject. The FDA Form 1572 used for every research trial requires the principal investigator to certify that all adverse events will be promptly reported. Sponsors and CROs carefully track these adverse reactions because they can often reveal contraindications (negative interactions for patients who experience a particular medical condition), drug-to-drug interactions, or side effects for experimental medications. As one example, a female subject in a study for liver cirrhosis had a significant adverse reaction to taking the study medication. This subject informed ZAIN RESEARCH that after taking the study medication, she experienced a menstrual period for an entire month and broke out in hives. The study coordinator, B.B., provided this information to SAMI ANWAR, who directed that this adverse event not be reported and that this subject continue to be enrolled in the study. Neither SAMI ANWAR nor ZAIN RESEARCH ever brought this adverse reaction to the sponsor, the CRO, or the principal investigator, Dr. N.

69. SAMI ANWAR also directed ZAIN RESEARCH staff to fraudulently record dispensation of the study drug on numerous studies. As one example, on a study involving scabies, the study medication, which was a topical cream, was not provided to the study subjects. Instead, SAMI ANWAR directed study coordinators, including L.D., to tell the subjects to squeeze the tubes of the study

medication into the trash, producing an empty tube that could be shown to auditors and monitors to make it appear as though the medication had been dispensed. If a tube was not emptied, SAMI ANWAR demanded to know why the study coordinators had not emptied the tubes and required that they did so. At SAMI ANWAR's direction, ZAIN RESEARCH staff would then fraudulently and falsely report in study documentation that the study medication had been dispensed as required, and that the subjects had not experienced any negative reactions to the cream.

70. ZAIN RESEARCH and SAMI ANWAR also falsified subject diaries, which were required to be completed by subjects, in order to hide the fraudulent study activity and continue billing for ineligible subjects and subjects who were not participating in the study. Subject diaries document the subject's subjective experience on the study as well as when medication is taken, when certain symptoms are experienced, etc. As one example, a pediatric constipation study conducted by ZAIN RESEARCH required subject diaries to be taken home and competed by subjects. SAMI ANWAR directed that these diaries not be provided to subjects, but instead be fraudulently completed by ZAIN RESEARCH personnel because if the subjects failed to complete them and did not bring them back, the subject could not continue on the study and ZAIN RESEARCH would not be able to further bill for that subject. As a result, at SAMI ANWAR's direction, ZAIN RESEARCH staff regularly fraudulently completed these diaries on behalf of the subjects, entering false information designed to make it appear as though the subjects were still eligible to participate. When one study coordinator, L.D., called study subjects to ensure that the information in the diaries was completed accurately, resulting in one subject being discontinued from the study, SAMI ANWAR became angry and directed L.D. to thereafter complete all subject diaries

herself, entering false and pre-determined information, to ensure that ZAIN RESEARCH could continue billing for each and every subject.

Pfizer and ICON Uncover Certain Aspects of the Fraud

71. In 2014 and 2015, Pfizer and ICON began conducting quality monitoring related to the Cholesterol Study. As part of this monitoring, Pfizer and ICON representatives conducted a number of onsite monitoring visits to assess ZAIN RESEARCH's compliance with applicable regulations and requirements. These individuals documented and raised significant concerns regarding the manner in which ZAIN RESEARCH and SAMI ANWAR were conducting these studies, the integrity of the study data being reported, and the safety of the subjects that had been enrolled. Specifically, these individuals informed Pfizer and ICON staff that ZAIN RESEARCH and SAMI ANWAR were: (1) enrolling subjects that did not qualify for the study; (2) excluding medical records from documentation that would disqualify subjects to hide their ineligibility; (3) creating medical histories to make subjects appear eligible; (4) enrolling the same subjects in multiple studies simultaneously; and (5) forging Dr. N's signature on relevant study documents. As a result of these allegations, Pfizer performed a for-cause audit regarding both Pfizer studies that ZAIN RESEARCH was performing for Pfizer: the Cholesterol Study and the Smoking Cessation Study.

72. The audits uncovered and documented critical deficiencies in ZAIN RESEARCH's conduct of both studies, and validated the concerns raised by the ICON and Pfizer monitors. With regard to the Cholesterol Study, the audit report documented and concluded that Dr. N, the purported principal investigator, was not exercising appropriate or meaningful oversight over the subject as required. The audit report documented that numerous signatures for Dr. N in study documentation did not appear to be Dr. N's signature, that the subjects' informed

consent was not appropriately documented or approved, that numerous ineligible subjects had been entered into the study, and that the medical history for subjects was not accurate or complete. The audit also noted that for each and every one of the 40 subjects in the Cholesterol Study, the documentation was materially incomplete, with "multiple essential documents throughout the regulatory binder" being documented with what appeared to be falsified Dr. N signatures, medical history information missing and insufficient to support the subject's enrollment into the study, and other significant issues. The audit recommended that, because ZAIN RESEARCH had not taken adequate corrective action when these issues were first pointed out, ZAIN RESEARCH's participation in the Cholesterol Study be terminated. In response, in August 2015, Pfizer terminated ZAIN RESEARCH's participation in the Cholesterol Study. The audit for the Smoking Cessation Study documented similar issues, and Pfizer terminated ZAIN RESEARCH's participation in the Smoking Cessation Study as well.

FDA Inspects ZAIN RESEARCH and Dr. N.

73. Following Pfizer's termination of ZAIN RESEARCH's participation in the Cholesterol Study, the FDA conducted an October 2015 inspection of ZAIN RESEARCH and Dr. N's participation in two studies: the Cholesterol Study, which had already been terminated by Pfizer in August 2015, and another study involving diabetic gastroparesis.

74. FDA's inspection also documented critical deficiencies on both studies, including: (a) the failure to obtain informed consent from study subjects; (b) enrollment of ineligible subjects that did not meet the inclusion criteria and/or fell under exclusion criteria; (c) failure to notify the sponsor regarding clinically significant laboratory results; (d) failure to report adverse events; (e) failure to maintain adequate study documentation and records, including medical histories,

dosage amounts, and concomitant medications; (f) failure to report risk to human subjects to the interdisciplinary review board; and (g) inaccurate and incomplete drug dispensation records regarding the investigational product. As a result of FDA's inspection, it issued a report of its findings and, on March 10, 2016, issued a warning letter to Dr. N, the purported principal investigator, concerning its findings.

75. As SAMI ANWAR and ZAIN RESEARCH understood, prospective sponsors and CROs typically require a lab and prospective principal investigator to disclose whether the laboratory or principal investigator have ever been inspected by FDA or been the subject of an FDA inspection and report such as the FDA's report and warning letter issued to ZAIN RESEARCH and to Dr. N. Therefore, as SAMI ANWAR knew, if SAMI ANWAR or ZAIN RESEARCH sought any future studies using Dr. N as principal investigator, they would be required to disclose that ZAIN RESEARCH and Dr. N had been cited by the FDA. As SAMI ANWAR knew, the FDA's findings meant that no sponsor or CRO would enter into a clinical trial agreement with ZAIN RESEARCH or Dr. N or pay him for any purported research. Accordingly, in 2016, following the FDA's report and warning letter, SAMI ANWAR began using a new business name, MID COLUMBIA RESEARCH, for the studies he was seeking to purportedly conduct, although SAMI ANWAR did not formally incorporate or form MID COLUMBIA RESEARCH until July 2017. SAMI ANWAR also found a new physician, Dr. Doe, to put forth as principal investigator, so he would not have to use Dr. N as a principal investigator. As just one example, as part of the site qualification process, Braeburn and Medpace required prospective labs to disclose whether they had been inspected by FDA and obtain a copy of any FDA reports issued. SAMI

ANWAR and ZAIN RESEARCH falsely indicated to Braeburn and Medpace that the "site" had not been the subject of an FDA inspection or citation report.

Defendants Fraudulently Obtained Approval for the Braeburn Study

76. It was part of the Conspiracy that the Defendants and their known and unknown co-conspirators made numerous false and fraudulent statements and misrepresentations in order to obtain approval to conduct the Braeburn Study, including, for example, the following:

a) Defendants, and other conspirators known and unknown to the Grand Jury, knowingly and intentionally created and submitted to Braeburn and Medpace a false and forged form FDA-1572, Statement of Investigator, bearing Dr. Doe's signature, dated November 9, 2016. Dr. Doe did not personally review or sign the FDA-1572 prior to its submission, nor did he "personally conduct or supervise" the investigation as the form falsely certifies. Defendants never intended Dr. Doe to "personally conduct or supervise" the Braeburn Study, but used his name and credentials in order to make it appear as though a licensed physician was conducting the study so that Braeburn and Medpace would approve it. As Defendants knew, Braeburn and Medpace would not have approved MID COLUMBIA RESEARCH's participation without a licensed physician's certification, on an FDA-1572, that he would personally conduct or supervise the investigation.

b) Defendants also knowingly and intentionally created and submitted to Braeburn and Medpace a false and forged Clinical Trial Agreement, bearing Dr. Doe's purported signature, dated November 8, 2016. Dr. Doe did not review or sign the Clinical Trial Agreement prior to Defendants submitting it. The Clinical Trial Agreement falsely

represented to Medpace and Braeburn that the study would "be conducted under the direction of [Dr. Doe], and that [Dr. Doe] shall be responsible for the oversight and direction of the study." The Clinical Trial Agreement also falsely represented that Dr. Doe and MID COLUMBIA RESEARCH would comply with all FDA rules and regulations, and would perform the study in compliance with the protocol. As Defendants knew, Braeburn and Medpace would not have approved MID COLUMBIA RESEARCH's participation without a Clinical Trial Agreement with a licensed physician stating that he would be responsible for the oversight and direction of the study, and that he would ensure that the study be performed pursuant to applicable regulations and the protocol.

Defendants' Fraudulently Enrolled Ineligible Subjects into the Braeburn Study

77. As part of the Braeburn Study, the Defendants, and other conspirators both known and unknown to the Grand Jury, enrolled a total of forty (40) subjects into the Braeburn Study who were all purportedly eligible to be subjects under the terms and conditions of the Clinical Trial Agreement and the protocol. In fact, as the Defendants knew, none of the subjects enrolled in the Braeburn Study were eligible under the terms of the protocol or the Clinical Trial Agreement. Nonetheless, it was part of the Conspiracy that the Defendants, and other known and unknown conspirators, sought and received hundreds of thousands of dollars in payments from Braeburn and Medpace for the purported visits of the ineligible subjects.

78. It was part of the Conspiracy that the Defendants, and other known and unknown conspirators, enrolled dozens of subjects into the Braeburn Study who the Defendants knew, at the time of their enrollment, were ineligible under the

terms of the Clinical Trial Agreement and the protocol. The Defendants did this with the specific intent of fraudulently obtaining the per-visit, per-subject payments from Braeburn and Medpace corresponding to the ineligible subjects, which ranged up to $1,800.00 per visit under the terms of the Clinical Trial Agreement, and totaled well over a quarter-million dollars in fraudulently obtained payments from Braeburn and Medpace before the Conspiracy was uncovered and stopped.

79. As the Defendants knew, the Clinical Trial Agreement made compliance with the protocol an explicit condition of the per-visit, per-subject payments. The protocol included specified inclusion criteria that any individual proposed as a subject for the Braeburn Study was required to meet in order to be eligible to be enrolled in the Braeburn Study. The protocol also included specified exclusion criteria, any one of which would make an otherwise qualifying proposed subject for the Braeburn Study ineligible.

80. For any clinical trial, compliance with the inclusion and exclusion criteria in enrolling subjects, as determined and verified by the clinical investigator, is essential for any of the results of the trial to be of value to the sponsor. Accordingly, Braeburn and Medpace provided the Defendants with standardized screening visit checklists that were required to be filled out per the protocol and reviewed by the clinical investigator, Dr. Doe, and signed and dated by him, affirmatively representing whether the proposed subject met all of the inclusion criteria and did not fall under any of the exclusion criteria.

81. In violation of the Clinical Trial Agreement and protocol, none of the 40 subjects in the Braeburn Study for which Defendants sought and received payment were seen, admitted, or had their medical condition or any of the inclusion or exclusion criteria assessed by Dr. Doe in determining their eligibility

to participate in the study, making each and every subject ineligible to participate in the study. If Braeburn and Medpace had known that Dr. Doe had not seen or admitted any of the subjects, and had not assessed any of their medical conditions or inclusion or exclusion criteria or determined them eligible for the study, Braeburn and Medpace would not have authorized payment for any of the subjects.

82. Additionally, despite knowing of the inclusion and exclusion criteria of the protocol, the Defendants, and other conspirators both known and unknown to the Grand Jury, enrolled dozens of individuals as subjects in the Braeburn Study that did not meet the inclusion criteria and met at least one of the exclusion criteria at the time of their initial screening. Nonetheless, the Defendants, and other conspirators both known and unknown to the Grand Jury, knowingly and intentionally submitted false and misleading information to Braeburn and Medpace to make it appear that these ineligible subjects were eligible. In this manner, the Defendants were able to defraud Braeburn and Medpace of hundreds of thousands of dollars in per-visit, per-subject payments for ineligible subjects.

83. The protocols' inclusion criteria included, but were not limited to, a requirement that the proposed subject had been treated with daily opioids for moderate to severe chronic lower back pain for a minimum of three (3) months (the Braeburn Study Protocol was amended in August of 2017 to clarify that certain new subjects with a documented history and diagnosis of chronic pain (not just lower back pain) were eligible). This inclusion criteria was essential to the efficacy of the Braeburn Study, which was attempting to evaluate the efficacy and safety of using injections of CAM2038 on subjects with a recent history of moderate to severe chronic pain currently being treated with opioids. If a person in fact had not been suffering from moderate to severe chronic pain for at least three (3) months, then enrolling that person as a subject in the Braeburn Study would not

in any way advance any understanding of the safety or efficacy of injections of CAM2038 for suffers of moderate to severe chronic pain. Similarly, if a person in fact had not been treating their moderate to severe chronic pain for at least three (3) months with daily opioids, then enrolling that person as a subject in the Braeburn Study would not in any way advance any understanding of the safety or efficacy of injections of CAM2038 as an alternative for suffers of moderate to severe chronic pain. Further, in each instance, inclusion of such an ineligible subject would corrupt the results of the Braeburn Study.

84. Despite knowing of this inclusion criteria and its essential role in the efficacy of the Braeburn Study, the Defendants, and other conspirators, both known and unknown to the Grand Jury, caused ineligible persons to be enrolled as subjects in the Braeburn Study who, as the Defendants knew, had not been suffering from moderate to severe chronic pain for at least three (3) months and/or were not being treated with opioids at all. If Braeburn or Medpace had been aware that subjects who did not meet this inclusion criteria were nonetheless being enrolled in the study they would not have paid the Defendants for any of the per-visit amounts corresponding to that subject.

85. The Braeburn Study inclusion criteria also included, but was not limited to, a requirement that all subjects be provided written informed consent prior to the conduct of any study-related procedures. In addition to being a cornerstone of modern medical research, the informed consent of a subject to conduct medical tests on that subject is needed in order for the results of that test to be usable and of any value, as well as to ensure that the subject is willingly participating in the study. Accordingly, the protocol required that all subjects sign approved informed consent forms, any revised informed consent forms, and that the date and time of the subject's signature on the informed consent form be

documented along with study personnel who conducted the informed consent process.

86. Despite knowing of this inclusion criteria and its essential role in the efficacy of the Braeburn Study, the Defendants, and other conspirators both known and unknown to the Grand Jury, knowingly falsified documentation submitted to Braeburn and Medpace in order to falsely represent that these subjects had provided informed consent when in fact they had not, either because the subject was never provided nor signed an informed consent form or because, contrary to the protocol, the nature of the study and its risks and benefits were not explained to the subject. When Braeburn and Medpace later became aware of the false representations related to the lack of informed consent of multiple subjects, as well as other false representations, they terminated MID COLUMBIA RESEARCH's participation in the Braeburn Study.

87. The Braeburn Study exclusion criteria included, but were not limited to, excluding as a subject any person who was an employee of the research site or an employee's family member. The protocol also required that the study be conducted ethically and consistent with good clinical practice, which would, among other things, prohibit enrolling as subjects employees of entities co-located with the research site that were also co-owned and co-operated by the same individual owner and operator of the research site, or the family members of such employees. The exclusion criteria and requirements of the protocol were essential to the integrity and efficacy of the Braeburn Study as they prevented the conflicts of interest inherent when employees of a research site or its owner and operator, or their family members, are enrolled as subjects in a clinical trial. Using employees or family members as subjects corrupts the results of any clinical trial and renders its findings, certainly as to those subjects, useless. Pursuant to the Clinical Trial

Agreement and the protocol, any employee of MID COLUMBIA RESEARCH, ZAIN RESEARCH, or Company A, or any family member of any employee, was ineligible to participate as a subject, and MID COLUMBIA RESEARCH was not eligible to receive payment from Braeburn and Medpace for any such subject.

88. If Braeburn and Medpace had been aware that subjects who were employees of Defendants or of Company A, or a family member of any employee, were nonetheless being enrolled in the study, they would not have paid the Defendants for any of the per-visit amounts corresponding to any of those subjects.

89. Only by way of example of the Conspiracy's fraudulent enrollment of ineligible subjects, the Defendants, and other conspirators, both known and unknown to the Grand Jury, knowingly and intentionally caused standard screening visit checklists and other eligibility and enrollment documentation for multiple subjects of the Braeburn Study, including but not limited to, Subject 068-017; Subject 068-027; Subject 068-028; Subject 068-034; Subject 068-035; and Subject 068-039, to be submitted to Braeburn and Medpace falsely representing that these subjects were eligible for enrollment as subjects in the Braeburn Study. Specifically, for example, the Defendants, and other conspirators, both known and unknown to the Grand Jury, falsely represented that the inclusion criteria of being treated with daily opioids for a minimum of three months prior to screening had been met, when, as the Defendants knew, Subject 068-017; Subject 068-027; Subject 068-028; Subject 068-034; Subject 068-035; and Subject 068-039 were not being treated with daily opioids at all.

90. For Subject 068-017; Subject 068-027; Subject 068-028; Subject 068-034; Subject 068-035; and Subject 068-039, the Defendants, and other conspirators, both known and unknown to the Grand Jury, caused a signature, purporting to be Dr. Doe's signature as the Investigator, without Dr. Doe's

knowledge or consent, to be forged on the standard screening visit checklists and other enrollment and eligibility documentation for each of those subjects all bearing dates between May 29, 2017, and September 20, 2017, affirmatively and falsely attesting that these subjects met all of the inclusion criteria of the Braeburn Study. As the Defendants knew, Dr. Doe did not screen any of the 40 subjects, including, for example, Subject 068-017; Subject 068-027; Subject 068-028; Subject 068-034; Subject 068-035; or Subject 068-039, as part of the Braeburn Study, did not determine their eligibility to participate in the Braeburn Study, and had no part in filling out or signing any of the corresponding standard screening checklists or other eligibility and enrollment documentation submitted to Braeburn and Medpace.

91. Based in part on the false screening visit checklists and other eligibility and enrollment documentation submitted to Braeburn and Medpace for Subject 068-017; Subject 068-027; Subject 068-028; Subject 068-034; Subject 068-035; and Subject 068-039, the Defendants sought over $50,000.00 from Braeburn and Medpace in payments directly tied to those ineligible subjects for which Defendants, and their known and unknown co-conspirators, falsely claimed eligibility.

92. Only by way of further example of the Conspiracy's fraudulent enrollment of ineligible subjects, the Defendants, and other conspirators, both known and unknown to the Grand Jury, knowingly and intentionally caused a standard screening visit checklist and other eligibility and enrollment documentation for Subject 068-011 to be submitted to Braeburn and Medpace falsely representing that this subject had a clinical diagnosis of moderate to severe chronic pain that had been treated with daily opioids for three months or more. In fact, as the Defendants knew, Subject 068-011 had no such clinical diagnosis and

the medical records held by the Defendants reflected that on April 12, 2017, the date of the falsified standard screening visit checklist, the subject was "present for lower back pain" with "no historical diagnoses." Based in part on the false screening visit checklists and other falsified materials submitted to Braeburn and Medpace for Subject 068-011, the Defendants claimed $14,325.00 from Braeburn and Medpace in payments directly tied to this ineligible subject. When Braeburn and Medpace later became aware of the false representations related to the eligibility of Subject 068-011, as well as other false representations, through a for-cause audit performed by Braeburn and Medpace personnel at the location of the Defendants' business in October 2018 (hereinafter the "October Audit"), they terminated MID COLUMBIA RESEARCH's participation in the Braeburn Study.

93. Only by way of further example of the Conspiracy's fraudulent enrollment of ineligible subjects, the Defendants, and other conspirators, both known and unknown to the Grand Jury, intentionally and fraudulently enrolled Subject 068-022 and Subject 068-027 in the Braeburn Study knowing that Subject 068-022 and Subject 068-027 were family members of an employee of MID COLUMBIA RESEARCH and SAMI ANWAR. Specifically, the Defendants knew that Subject 068-022 was the father of the lead MID COLUMBIA RESEARCH study coordinator for the Braeburn Study and Subject 068-027 was a cousin of that same study coordinator. Both Subject 068-022 and Subject 068-027 were therefore ineligible to participate in the Braeburn Study. Based in part on the false representations regarding the eligibility of Subject 068-022 and Subject 068-027, the Defendants sought a total of $22,800 from Braeburn in payments directly tied to those ineligible subjects. If Braeburn and Medpace had been aware that Subject 068-022 or Subject 068-027 were ineligible family members of MID COLUMBIA RESEARCH's lead study coordinator, they would not have paid the

Defendants for any of the respective per-visit amounts corresponding to those subjects, nor would they have permitted either to participate in the study.

94. It was also part of the Conspiracy to falsify medical records of persons who were ineligible as subjects for the Braeburn Study to make it appear that these persons had the appropriate diagnosis and opioid use and therefore eligible for enrollment, and included these false records as part of the fraudulent eligibility and enrollment documentation submitted to Braeburn and Medpace. The Defendants did this with the specific intent to deceive Braeburn and Medpace and to collect per-visit payments for ineligible subjects.

95. By way of example only, the Defendants, and other conspirators both known and unknown to the Grand Jury, submitted, in or about July 2017, falsified medical records and other eligibility and enrollment documentation to Braeburn and Medpace for Subject 068-030, an employee of SAMI ANWAR and Company A, falsely representing that that subject suffered from moderate to severe chronic pain, and also representing that she had no history of asthma. In November 2017, the Defendants, and other conspirators both known and unknown to the Grand Jury, submitted false medical records purportedly from Company A for Subject 068-030 to a different clinical study, regarding asthma, that purportedly indicated that Subject 068-030 suffered from asthma and had no history of any chronic pain. These Company A medical records contained a forged signature of Dr. Doe, who was completely unaware of the asthma study and did not review any medical records for it nor play any role in it. Nonetheless the Defendants claimed a total of $10,725.00 from Braeburn and Medpace for the per-visit payments for Subject 068-030. If Braeburn and Medpace had been aware that the Defendants, and other conspirators both known and unknown to the Grand Jury, falsified medical records to justify the eligibility of subjects, they would not have paid the Defendants for

any of the costs or per-visit amounts corresponding to that subject and would have terminated MID COLUMBIA RESEARCH's participation in the study.

Defendants Fraudulently Obtained Per-Visit Payments from Braeburn

96. It was part of the Conspiracy, for the Defendants, and other conspirators, both known and unknown to the Grand Jury, to fraudulently seek and obtain per-visit payments for subjects of the Braeburn Study not only for subjects who were never eligible to participate in the trial to begin with, but also for visits that were not completed as required by the Clinical Trial Agreement and the protocol. In this manner, the Defendants received hundreds of thousands of dollars in payments from Braeburn and Medpace for falsified subject visits that never took place.

97. Under the Clinical Trial Agreement and the protocol, in addition to securing per-visit subject payments, the weekly subject visits, if properly and actually conducted, could cause a subject to become ineligible to continue to participate in the study, for example, because of abnormal test results or the amount of pain reported by the subject. In addition, a subject not showing up for weekly visits would likely cause the subject to become ineligible to continue to participate. In the event that a subject was discontinued from the study, as the Defendants knew, they could not continue to claim per-visit subject payments for that subject. Accordingly, it was part of the Conspiracy to falsify the documentation of subjects' weekly visits and submit false documentation to Braeburn and Medpace for each weekly visit, to create the appearance that the subjects had been present for their weekly visits, that the weekly visits had been properly conducted per the protocol, and that none of the criteria in the protocol that would render the subject ineligible to continue had been triggered.

98. Per the terms of the Clinical Trial Agreement compliance with the different weekly visit requirements in the protocol was a necessary condition of the per-visit subject payments from Braeburn and Medpace. The protocol required enrolled subjects to visit the business location of the Defendants each week during the study. The protocol provided for the specific required steps that had to be accomplished at these different weekly visits, including the administration of the CAM 2038 shot as well as the dispensing of rescue medication. By way of example only, some weekly visits required obtaining clinical laboratory assessments through blood draws and laboratory testing, while other weekly visits required urine tests for drug screening, and still other weekly visits required electrocardiograms (ECGs) to be conducted on the subjects. Further, all of the weekly visits required obtaining the vital signs of the subjects and all of the weekly visits required written progress notes documenting aspects of the weekly visit, including any adverse events reported by the subjects. For their weekly participation subjects were entitled, under the protocol, to payment of $75 per visit.

99. The protocol required that the Investigator conduct the weekly visits or, to the extent any activities were delegated, to have direct oversight of all delegated activities and to document any delegation of responsibilities. In fact, as the Defendants knew, Dr. Doe, as the Investigator, did not conduct any of the weekly visits, did not delegate any activities to others, and did not have direct oversight, or any oversight, of the activities of any of the Defendants, and/or other conspirators both known and unknown to the Grand Jury, related to subject weekly visits. Many of the purported weekly visits did not take place at all, while many other subjects attended visits only to receive their weekly check for participating in the study, and received neither the CAM 2038 study drug, nor the rescue medication.

100. By way of example only, the protocol required that the Investigator, or his medically qualified delegate, take and record subject vital signs such as temperature, blood pressure, pulse rate, pulse oximetry, and respiratory rate, at each weekly subject visit. However, subjects often did not attend their weekly visits and accordingly the Defendants, and other conspirators both known and unknown to the Grand Jury, routinely falsified documentation showing that subjects' vital signs had been taken, validly recorded, and, as indicated by the forged signature of Dr. Doe, reviewed by the Investigator to assess the results for any clinical significance. If Braeburn and Medpace had been aware that any of the weekly vital signs were being falsely or fraudulently represented, they would not have paid the Defendants for the corresponding subject and the corresponding weekly visit and would have terminated MID COLUMBIA RESEARCH's participation in the study.

101. By way of further example only, the protocol required that each subject be seen by the Investigator or his medically qualified delegate at each weekly visit and that the Investigator document the notes of the visit, including any adverse events reported by the subject or observed by the Investigator. However, as subjects often did not attend their weekly visits, the Defendants, and other conspirators both known and unknown, routinely created fraudulent progress notes falsely stating that the subject had visited, and falsely recording events, including but not limited to, the dispensing of rescue medication to the subject, statements that a subject purportedly made or did not make, whether the subject received an injection, and whether certain required assessments had been performed.

102. These false and fraudulent progress notes often contained the forged signature of Dr. Doe, as the Investigator, falsely indicating that he had reviewed the progress notes for any clinically significant events when, as the Defendants,

and other conspirators both known and unknown to the Grand Jury, knew, Dr. Doe had no knowledge that his signature was being forged, had not reviewed the progress note nor seen the subject or any of the subject documentation for the visit, and had not had any involvement with the purported weekly visit of the subject. If Braeburn and Medpace had been aware of any one of these false and fraudulent progress notes for visits that did not take place, or forged signatures of Dr. Doe on the purported progress notes, they would not have paid the Defendants for the corresponding weekly visit for that subject and would have terminated the study.

103. By way of further example only, the protocol required that ECGs be performed on subjects on certain specified weekly visits. The protocol specified when the ECGs needed to be performed in relation to, for instance, injections of CAM2038. The protocol further required that the Investigator, or other medically-qualified individuals that he may delegate, review all ECGs to ascertain the subject's heart activity, including whether the subject was experiencing any abnormalities and whether any such abnormalities were clinically significant, presented any health or safety concerns, and whether referral to a cardiologist was necessary.

104. It was part of the Conspiracy to falsify ECGs by performing them on employees of MID COLUMBIA RESEARCH and SAMI ANWAR, who were not subjects in the Braeburn Study, and then fraudulently submitting the results to Braeburn and Medpace, falsely representing them to be those of various subjects. Specifically, the Defendants, and other conspirators both known and unknown to the Grand Jury, would routinely falsify the date and time of the ECGs and forge Dr. Doe's signature or initials to make it appear that the ECGs had been conducted and reviewed as required by the protocol when in fact they had not. When Braeburn and Medpace later became aware of the false representations related to

purported subject ECGs, as well as other false representations, through the October Audit, they terminated MID COLUMBIA RESEARCH's participation in the Braeburn Study. Had Braeburn/Medpace been aware of any one of these false and fraudulent ECGs they would not have paid the Defendants for the corresponding weekly visit for that subject.

105. By way of further example only, the protocol required that on certain specified weeks during the Braeburn Study a 12-panel urine drug screen would be administered to test for the presence of certain drugs of abuse including but not limited to cocaine, methamphetamines, and barbiturates. The protocol required that the results of these subject urine drug screen tests be provided to Braeburn and Medpace as part of ensuring continued subject eligibility and for data collection purposes. However, because subjects often did not attend their weekly visits and did not receive the rescue medication, meaning they would not test positive for the opioids that Defendants falsely claimed they were taking, the Defendants, and other conspirators both known and unknown, would sometimes use the urine samples of some patients of Company A, who the Defendants knew would (unlike the subjects) test positive for opioids. Defendants, and their known and unknown co-conspirators, would then provide the resulting false and fraudulent urine samples to Braeburn and Medpace's laboratory as though they had come from subjects. Had Braeburn and Medpace been aware of any one of these false and fraudulent urine drug screening tests, they would not have paid the Defendants for the corresponding weekly visit of that subject and would have terminated MID COLUMBIA RESEARCH's participation in the study.

106. By way of further example only, the protocol required that on certain specified weeks during the Braeburn Study that the Investigator, or his medically-qualified delegate, take blood samples from the subjects to be tested for non-drug

related items such as red blood cell count, mean corpuscular volume, mean corpuscular hemoglobin concentration, and platelets. The protocol required that the blood samples be submitted to Medpace's laboratory for testing and that the Investigator review and sign all laboratory reports in order to document the data collection for the study, the appropriate safety monitoring of subjects, and any clinically significant items or other abnormalities.

107. Because subjects frequently did not attend their weekly visits, the Defendants, and other conspirators both known and unknown to the Grand Jury, directed and participated in the collection of blood samples from persons other than subjects in order to submit blood samples to a central laboratory as required by the protocol. SAMI ANWAR designated one MID COLUMBIA RESEARCH study coordinator to provide fraudulent blood samples, and directed other employees of SAMI ANWAR and MID COLUMBIA RESEARCH to draw that study coordinator's blood and to falsely label it as being from subjects who did not attend their weekly visit, and then to submit the samples to the laboratory for testing.

108. At times the Defendants, and other conspirators both known and unknown and to the Grand Jury, directed and participated in stealing blood samples taken from patients of Company A who had no knowledge of, and did not consent to, the use of their blood samples in the Conspiracy. At SAMI ANWAR's direction, at times Company A employees would tell Company A patients that they qualified for a free laboratory blood test, draw the patients' blood, falsely label the blood as being from the Braeburn Study subject who had not attended the weekly visit, and then submit the fraudulent blood sample for testing.

109. Whether stolen from patients or taken from employees of SAMI ANWAR, the Defendants, and other conspirators both known and unknown to the

Grand Jury, knowingly and intentionally used the laboratory results of the stolen and otherwise ill-gotten blood samples to make it appear that they were complying with the protocol in order for the Defendants to fraudulently obtain the corresponding per-visit payments from Braeburn and Medpace, which were typically worth hundreds of dollars more than the subject weekly visits that did not require blood testing. Moreover, a failure to submit blood laboratory results as required by the protocol for any one subject would have precluded receiving any further payment from Braeburn and Medpace for that subject.

110. Moreover, if Braeburn and Medpace had been aware of the Defendants' theft and use of stolen blood, they would not have paid the Defendants for the corresponding weekly visit for those subjects, and would have terminated MID COLUMBIA RESEARCH's participation in the study.

Defendants Fraudulently Obtained Controlled Substances and Misrepresented Their Dispensation of Controlled Substances

111. As part of the Conspiracy, Defendants, and their known and unknown co-conspirators, fraudulently obtained and fraudulently misrepresented their dispensation of the controlled substances that were part of the Braeburn Study, including, for example, the following:

112. Defendants' orders of the morphine rescue medication and the hydrocodone rescue medication were fraudulent. Morphine and hydrocodone are Schedule II controlled substances. As such, these medications can only be ordered for legitimate medical or research purposes by an authorized registrant with a registration for Schedule II controlled substances, and only on a DEA-222 form signed by an authorized signator of the registrant. In the case of the Braeburn Study, Dr. Doe was the registrant, and was the only person authorized by DEA to sign a DEA-222 form. The DEA-222 forms used by Defendants to obtain the hydrocodone and morphine that was purportedly for the Braeburn study, however,

were not signed by Dr. Doe. Instead, SAMI ANWAR forged Dr. Doe's signature, and Defendants knowingly submitted the forged DEA-222 using Dr. Doe's DEA registration number and forged signature. Moreover, Defendants did not order the hydrocodone or morphine for legitimate use in the Braeburn Study, but instead as part of the Conspiracy, to make it look as though the study was being conducted legitimately and pursuant to the protocol, and so Defendants could fraudulently bill and obtain payment from Braeburn and Medpace for the study.

113. Defendants knowingly and intentionally ordered, obtained, and dispensed the CAM 2038 buprenorphine shot, the morphine rescue medication, and the hydrocodone rescue medication for study subjects who were not eligible to participate in the study, including, but not limited to, the specific ineligible subjects discussed above. Defendants ordered the CAM 2038 buprenorphine, the morphine, and the hydrocodone to make it appear as though the study subjects were legitimate study participants, and so Defendants could fraudulently bill and obtain payment from Braeburn and Medpace for these ineligible participants.

114. Defendants knowingly and intentionally ordered, obtained, and removed from the Defendants' drug dispensary the CAM 2038 buprenorphine shot, the morphine rescue medication, and the hydrocodone rescue medication for purported study subjects who were not actually participating in the study or attending their weekly visits. Defendants ordered the buprenorphine, the morphine, and the hydrocodone to make it appear as though the purported study subjects were participating in the study when in fact they were not, and so Defendants could fraudulently bill and obtain payment from Braeburn and Medpace for these supposed participants who were, in fact, not participating in the study.

115. Although Defendants removed the CAM 2038 buprenorphine shot from the Defendants' drug dispensary, because most of the purported study participants were, in fact, neither eligible for nor actually participating in, the study, and therefore did not come in for their study visits as the protocol required, the CAM 2038 buprenorphine study drug was frequently not provided to the study subjects. Instead, SAMI ANWAR directed his employees to shoot the CAM 2038 buprenorphine shots down the drain, so that the syringe containing the CAM 2038 buprenorphine shot for that particular research subject, for that particular visit, would be empty and it would appear as though the CAM 2038 buprenorphine shot had been provided to the study subject as the protocol required. At SAMI ANWAR's direction, the empty syringes were then collected and provided to Medpace and Braeburn in their monitoring visits, to make it appear as though the study was being conducted pursuant to the protocol. SAMI ANWAR also directed that MID COLUMBIA RESEARCH employees complete false documentation in the subject study binder falsely reflecting that the CAM 2038 buprenorphine study drug had been provided to the subject as the protocol required.

116. SAMI ANWAR further directed his employees, including employees of MID COLUMBIA RESEARCH, to submit falsified electronic entries into Medpace's Interactive Response Technology (IRT), a web-based computer interface between MID COLUMBIA RESEARCH and Medpace used to track MID COLUMBIA RESEARCH's dispensation of both rescue medications and the CAM 2038 syringes. All IRT submissions to Medpace from the Defendants traveled in interstate wires through the Medpace servers located in Cincinnati, Ohio.

117. SAMI ANWAR directed the creation of false subject binder documentation and the submission of false IRT data to Medpace in order to make

it appear to Medpace and Braeburn that the CAM 2038 syringes were being dispensed for subjects when in fact they were not. This allowed MID COLUMBIA RESEARCH to falsely bill Medpace and Braeburn for the visit, and to continue billing Medpace and Braeburn for that purported study subject for future visits.

118. Similarly, although Defendants removed the morphine rescue medication and the hydrocodone rescue medication from the Defendants' drug dispensary, because most of the purported study participants were, in fact, neither eligible for nor actually participating in, the study, and therefore did not come in for their study visits as the protocol required, the rescue medication was frequently not provided to the study subjects. Instead, SAMI ANWAR directed that MID COLUMBIA RESEARCH employees put the removed rescue medication into plastic bags labeled "No-Show" and hid the bags in a box labeled "B-Study" in the attic of the Defendants' business location, along with empty pill bottles that Defendants falsely stated had been provided to subjects. SAMI ANWAR further directed his employees, including employees of MID COLUMBIA RESEARCH, to falsify entries into the Medpace IRT to make it appear to Medpace and Braeburn that rescue medications were being dispensed to subjects when in fact they were not. SAMI ANWAR directed these actions to make it appear as though the study was being conducted and the rescue medication being dispensed pursuant to the protocol, and so that the amount of rescue medication in the Defendants' drug dispensary would match the amount that Defendants falsely represented had been provided to subjects. SAMI ANWAR also directed his employees, including employees of MID COLUMBIA RESEARCH, to complete false documentation in the subject study binder falsely reflecting that the rescue medication had been provided to the subject as the protocol required. SAMI ANWAR directed these

actions be performed so that Defendants could bill Medpace and Braeburn for the visit, and continue billing Medpace and Braeburn for that purported study subject for future visits.

Defendants Fraudulently Concealed Their Scheme

119. As part of the Conspiracy, Defendants, and their known and unknown co-conspirators, not only knowingly and intentionally concealed the truth from Braeburn and Medpace, but made numerous misrepresentations and false statements in order to prevent Medpace and Braeburn from discovering the Conspiracy.

120. Throughout the Braeburn Study, as part of the Conspiracy, SAMI ANWAR would fraudulently pose as Dr. Doe, without his knowledge or consent, on the phone in conversations with Medpace and Braeburn when a representative from Medpace or Braeburn called MID COLUMBIA RESEARCH or wanted to speak to Dr. Doe. SAMI ANWAR did this in order to prevent detection of the Conspiracy; Defendants knew that Dr. Doe was not conducting or supervising the Braeburn Study and was not knowledgeable about the Braeburn Study or any of the subjects, and that if Medpace or Braeburn were to contact Dr. Doe, they would discover the Conspiracy.

121. In December 2016, Medpace and Braeburn requested from MID COLUMBIA RESEARCH the mobile phone number for Dr. Doe, whom they believed to be the Investigator, in case Medpace or Braeburn needed to discuss the study with Dr. Doe after hours or when he was out of the office, including in the event of an emergency. Defendants knew that Dr. Doe was not conducting or supervising the Braeburn Study and was not knowledgeable about the Braeburn Study, and that if Medpace or Braeburn contacted Dr. Doe, they would discover the Conspiracy. Therefore, in order to prevent Braeburn and Medpace from

uncovering the Conspiracy, at SAMI ANWAR's direction, MID COLUMBIA RESEARCH instead provided the number for one of SAMI ANWAR's cellular phones.

122. In September 2017, a routine monitoring visit by Medpace revealed certain inconsistencies in subject binder and other study documentation. In addition, in September of 2017, Medpace received an anonymous call from an employee of MID COLUMBIA RESEARCH who advised that, among other things, subject diaries were being forged, subject medical records were being falsified, and rescue medications and CAM 2038 shots were not actually being dispensed as represented. Based on the inconsistencies and the employee's allegations, Medpace and Braeburn announced to MID COLUMBIA RESEARCH that they would be conducting a for-cause audit on October 11 and 12, 2017 (the October Audit). Medpace and Braeburn explained that the audit would involve the review of documentation related to research subjects, data verification, and drug dispensation and administration. In response to the upcoming audit, SAMI ANWAR directed that MID COLUMBIA RESEARCH perform a reconciliation comparing the number of pills of morphine and hydrocodone that its records falsely reflected had been provided to research subjects as rescue medication with the number of pills that the Defendants' drug dispensary had actually removed and place in the "No Show" bags. SAMI ANWAR directed this reconciliation because he knew that Medpace and Braeburn's audit would be verifying that all of the rescue medication that MID COLUMBIA RESEARCH's subject binders had reflected as being provided to subjects had actually been removed from the drug dispensary. The reconciliation performed by MID COLUMBIA RESEARCH revealed that approximately 590 hydrocodone pills that MID COLUMBIA RESEARCH's records falsely reflected were provided to research subjects were

still in the drug dispensary shared by Company A, and ZAIN RESEARCH and MID COLUMBIA RESEARCH. SAMI ANWAR therefore directed that these pills be removed from the drug dispensary to conceal the Conspiracy from the Medpace and Braeburn auditors. Defendants, and their known and unknown conspirators, then placed the pills in a sealable reusable plastic baggie, and placed the baggie in SAMI ANWAR's desk drawer in his office so that it would appear to Braeburn and Medpace that all of the rescue medication had been provided to research subjects as MID COLUMBIA RESEARCH's subject binders falsely reflected. In January of 2018, pursuant to the execution of a search warrant, the DEA found a sealable reusable plastic baggie in SAMI ANWAR's desk drawer in his office containing 590 hydrocodone pills.

123. Defendants knew that Braeburn and Medpace would also be reviewing subject binders to ensure that the Braeburn Study was being conducted pursuant to the protocol and that each of the subjects for which MID COLUMBIA RESEARCH was billing Braeburn and Medpace were making weekly visits, having vital signs and other study data drawn, receiving the study drug, and receiving rescue medication. Because the vast majority of the study subjects were not, in fact, actually participating in the study, SAMI ANWAR directed that MID COLUMBIA RESEARCH employees falsify this information in preparation for the October Audit. At SAMI ANWAR's direction, MID COLUMBIA RESEARCH employees falsified subject study attendance for their visits, vital sign data, study drug injections, receipt of the rescue medication, progress notes from the study participant, including purported pain levels and experience on the study, and study results. At SAMI ANWAR's direction, when MID COLUMBIA RESEARCH employees had "completed" the binder by falsifying the necessary information, they placed the binder in SAMI ANWAR's office for him to review

the documentation and forge Dr. Doe's signature to make it appear as though the information had been reviewed by the Investigator. Once SAMI ANWAR had done so, the binder was ready for review by Braeburn and Medpace.

124. Defendants' efforts to falsify these subject binders in advance of the audit were unsuccessful. The October Audit documented that: (1) subject signatures on revised consent forms appeared to be falsified; (2) the subject binders did not contain sufficient medical documentation to support subject eligibility based on daily opioid use or a history of chronic pain; (3) MID COLUMBIA RESEARCH had altered documentation without basis to make the subjects appear eligible; (4) the abnormalities documented in the majority of the ECGs were not adequately evaluated; (5) ECG results appear to have been doctored or falsified; (6) progress notes were not accurate, and appeared to have been done from a template; and (7) adverse events were not accurately or adequately reported, with almost no adverse events listed for the subjects. Ultimately, the auditors considered many of these findings critical and recommended that all data from MID COLUMBIA RESEARCH be thrown out and that MID COLUMBIA RESEARCH's participation be terminated, which Braeburn and Medpace did on October 23, 2017.

125. Because the Braeburn study was focused on opioid users who experienced moderate to severe chronic pain, one important aspect of the study was study subjects' own subjective perception about how the CAM 2038 buprenorphine injection managed their chronic pain, and how they felt on a daily basis. Therefore, as part of the protocol, study subjects were required to complete a daily diary documenting their subjective pain experience, the time of the day, and the need for any rescue medication. Because the vast majority of the study subjects were not experiencing chronic pain, were not users of prescription opioids,

and/or were not actually participating in the study, and therefore none of the subjects completed subject diaries, at SAMI ANWAR's direction, MID COLUMBIA RESEARCH employees falsified these subject diaries, which were required to be completed by the study subjects themselves, in anticipation of the October Audit. At SAMI ANWAR's direction, virtually all MID COLUMBIA RESEARCH employees participated in the falsification of subject diaries, so that different subject diaries would contain different-looking handwriting, and it would appear to the auditors that the subjects had completed the diaries themselves. Because there were more purported study subjects who were not actually participating in the study than available MID COLUMBIA RESEARCH employees, SAMI ANWAR directed that the MID COLUMBIA RESEARCH employees hold their pens differently for different purported subjects, so that the handwriting would not look identical and it would appear that the subjects had completed the diaries themselves. At SAMI ANWAR's direction, MID COLUMBIA RESEARCH employees not only falsified the subject diaries, but completed them with information calculated to show the study subjects' pain levels were decreasing, so it would appear as though the study was progressing as intended and the study subject would appear to continue to be eligible so that MID COLUMBIA RESEARCH could continue billing Braeburn and Medpace for that subject.

126. Defendants' efforts to falsify subject diaries were ultimately unsuccessful, in part, because, unknown to Defendants, Medpace had obtained a number of subject diaries during their September 2017 monitoring visit. Accordingly, when Defendants presented the newly falsified diaries to the Medpace and Braeburn auditors during the October Audit, the auditors were able to compare the two sets of diaries for the same subjects, and document that

Defendants had altered the diaries to make it appear as though the subjects were still eligible for the study. The October Audit specifically documented that subject diaries for Subject 068-012, Subject 068-013, Subject 068-014, Subject 068-015, and Subject 068-018 that had been obtained during the September monitoring visit did not support continued eligibility, and that by the time of the October Audit, MID COLUMBIA RESEARCH had replaced those subject diaries with new falsified subject diaries containing falsified data that did support subject eligibility. Ultimately, the auditors considered this finding critical and recommended that all data from MID COLUMBIA RESEARCH be thrown out and that MID COLUMBIA RESEARCH's participation be terminated, which Braeburn and Medpace did on October 23, 2017.

Defendants' Conspiracy Extended to a Proposed Study Involving GHB

127. The Conspiracy was not restricted to the studies specifically referenced above, but included other studies. For example, on May 12, 2017, SAMI ANWAR submitted an application to the DEA to conduct research using GHB as a study drug in a proposed study regarding patients with narcolepsy, which is a sleep disorder. SAMI ANWAR's application falsely represented that Dr. Doe would also be the clinical investigator on this study.

128. As with the Braeburn Study, Dr. Doe was never intended to personally conduct or supervise any study involving GHB. In fact, he was unaware that the study even existed at the time of the application's submittal, and only learned of it much later when shown the application by DEA investigators. SAMI ANWAR forged Dr. Doe's signature on the application to the DEA and on documents submitted in support of the application, including a falsified curriculum vitae on which SAMI ANWAR forged Dr. Doe's signature and which contained false information.

129. SAMI ANWAR's application for the GHB Study was not been approved because neither DEA nor Flamel, nor INC Research were ever able to get in touch with Dr. Doe, despite repeated efforts. In September 2017, after Dr. Doe first became aware that SAMI ANWAR used his name and forged his signature on the GHB Study application, Dr. Doe withdrew the application.

Defendants' Conspiracy Included Attempting to Influence and Intimidate Those with Knowledge of the Conspiracy

130. As part of the Conspiracy, Defendants, and their known and unknown co-conspirators, repeatedly attempted to silence, discredit, and intimidate individuals with knowledge of the Conspiracy whenever such individuals stopped working for the Defendants or were otherwise perceived by the Defendants as no longer being willing to protect the Conspiracy from discovery by sponsors, CROs, governmental regulators, and law enforcement.

131. For example, L.D., H.E., D.G., J.H., Dr. D.J., and Dr. N had knowledge of the Conspiracy's activities between November 2013 and July 2016, including, without limitation, direct and indirect knowledge of: (1) ZAIN RESEARCH and SAMI ANWAR's fraudulent enrollment of ineligible subjects; (2) SAMI ANWAR's forging Dr. N's signature and posing as Dr. N on the phone to hide the fact that a licensed physician was not conducting the study; (3) ZAIN RESEARCH and SAMI ANWAR's electronic submission of fraudulent study data to sponsors and monitors; (4) ZAIN RESEARCH and SAMI ANWAR's fraudulently completing subject diaries; (5) ZAIN RESEARCH and SAMI ANWAR's failure to report adverse events; and (6) ZAIN RESEARCH and SAMI ANWAR's fraudulent obtaining of investigational product and falsely reporting that it had been dispensed per the protocols.

132. Similarly, A.C., J.B., H.E., D.G., J.H., Dr. D.J., and, later, Dr. Doe, had knowledge of the Conspiracy's activities between July 2016 and November

2018, including the Conspiracy's activities related to the Braeburn Study, and including, without limitation, direct and indirect knowledge of: (1) Defendants' fraudulent enrollment of ineligible subjects; (2) SAMI ANWAR's forging Dr. Doe's signature and posing as Dr. Doe on the phone to hide the fact that a licensed physician was not conducting the study; (3) Defendants' electronic submission of fraudulent study data to sponsors and monitors; (4) Defendants' fraudulently completing subject diaries; and (5) Defendants' fraudulent obtaining of investigational product (including scheduled controlled substances) and falsely reporting that it had been dispensed per the protocols.

133. By way of example only, in February of 2016, L.D. resigned from ZAIN RESEARCH over concerns about the fraud L.D. was being asked to participate in. As SAMI ANWAR knew, L.D. had knowledge of the Conspiracy.

134. After resigning, L.D. did not want to return to the Defendants' business premises because of L.D.'s fear of SAMI ANWAR. However, L.D. had left three personal items at the business premises of the Defendants of great personal and sentimental value: a framed picture L.D.'s minor child had drawn; a Non-Commissioned Officer Creed plaque from L.D.'s military service; and a military deployment patch. Consequently, L.D. requested that a then current employee of ZAIN RESEARCH, referred to herein as Y.R., retrieve these personal items from the Defendants' business premises on behalf of L.D.. At that time, rather than assist in this process, SAMI ANWAR called the Richland Police Department and falsely reported that certain confidential documents had been stolen from his business. SAMI ANWAR also confronted his employee Y.R. regarding the purportedly stolen confidential documents. As a result, L.D. contacted the Richland Police Department investigating officer and explained that Y.R. had merely been retrieving L.D.'s personal items at L.D.'s request. Upon

further investigation, including interviewing Y.R. and re-interviewing SAMI ANWAR about the supposedly stolen confidential documents, the investigating officer determined that SAMI ANWAR's report of theft was unfounded and that in fact no confidential documents had been stolen as SAMI ANWAR had falsely claimed. However, these actions by SAMI ANWAR placed L.D. in greater and continued fear of SAMI ANWAR and of speaking out regarding L.D.'s knowledge of the Conspiracy.

135. By way of further example only, on July 5, 2017, prior to the DEA's investigation of the Conspiracy, but subsequent to FDA's inspection and warning letter, SAMI ANWAR made a fraudulent complaint to the FDA's Office of Science Investigation regarding Dr. D.J., a former business partner of SAMI ANWAR's with whom SAMI ANWAR had had a falling out. As SAMI ANWAR knew, Dr. D.J. had gained knowledge of the Conspiracy while working for SAMI ANWAR.

136. SAMI ANWAR made the fraudulent complaint to the FDA in the name of a then-current employee of the Defendants' in an attempt to mask the true source of the complaint. In the fraudulent complaint to the FDA SAMI ANWAR falsely alleged, among other things, that Dr. D.J. had engaged in the following prohibited actions while conducting the Braeburn Study: 1) enrolling subjects into the study who did not participate in required visits; 2) submitting blood samples from sources other than the subjects while falsely claiming they were from the subjects as required by the Braeburn Study; 3) altering or attempting to alter medical records; 4) falsifying curriculum vitae of a study investigator; and 5) improper and fraudulent handling of hydrocodone and morphine.

137. In January of 2018, the FDA found that the allegations contained in the fraudulent complaint were unsubstantiated as to Dr. D.J.. In fact, as alleged

herein, SAMI ANWAR was committing each of these acts on the Braeburn Study, as well as other clinical research trials before, during, and after he made the fraudulent complaint.

138. Continuing the pattern of attempts to silence and intimidate persons with knowledge of the Conspiracy no longer under his direct control, on August 29, 2017, SAMI ANWAR physically threatened Dr. N at the Defendants' place of business. As referenced above, Dr. N had been a principal investigator on multiple fraudulent clinical research trials conducted by the SAMI ANWAR and ZAIN RESEARCH. However, in August of 2017, Dr. N had withdrawn from his partnership and employment with SAMI ANWAR and ZAIN RESEARCH based on concerns of fraud being committed on clinical research trials, among other things. SAMI ANWAR's aggressive conduct towards Dr. N, on August 29, 2017, which included stealing Dr. N's cellular telephone in an attempt to prevent Dr. N from video recording SAMI ANWAR's aggressive behavior, resulted in the Richland Police Department being called to the disturbance. Upon the police arrival, SAMI ANWAR falsely stated to the investigating officer that Dr. N had been the aggressor and that he, SAMI ANWAR, had merely attempted to defend himself. SAMI ANWAR's false statements to the police were contrary to video evidence and the investigating officer placed SAMI ANWAR under arrest.

139. A few days later, on September 1, 2017, three female employees of the Defendants, submitted complaints to the Washington State Department of Health claiming, among other things, that Dr. N had sexually harassed them. These three complaints were nearly identically worded and simultaneously submitted. During that same period of time SAMI ANWAR coerced one of the three female employees," A.C.," to file a restraining order, for which SAMI

ANWAR paid the cost thereof, against Dr. N based on false allegations of sexual misconduct.

140. In December of 2017, the Defendants continued their efforts to silence and intimidate former employees with knowledge of the Conspiracy. At that time a medical provider with initials J.H., resigned from employment with the Defendants. As SAMI ANWAR knew, J.H. had knowledge of the Conspiracy.

141. Shortly after J.H.'s resignation the Defendants attempted to collect false complaints against J.H. from patients and staff. The Defendants' efforts included SAMI ANWAR barricading a medical patient, that patient's spouse, and that patient's two-year old child, in a room for an extended period of time while demanding that the patient sign a false Washington State Department of Health complaint against J.H.. However, the patient and the patient's family were able to escape SAMI ANWAR without signing anything.

142. After SAMI ANWAR gained actual knowledge of the DEA's investigation of the Conspiracy, the Defendants, and their known and unknown co-conspirators, continued to attempt to silence, discredit, and intimidate individuals with direct knowledge of the Conspiracy whenever such individuals stopped working for the Defendants or were otherwise perceived by the Defendants as no longer being willing to protect the Conspiracy from discovery by sponsors, CROs, governmental regulators, and law enforcement.

143. On January 24, 2018, the DEA executed a search warrant at the business premises of the Defendants. At that time, SAMI ANWAR gained direct knowledge of the DEA's criminal investigation of the Conspiracy. Specifically, the DEA provided SAMI ANWAR a copy of the search warrant that explicitly stated that the DEA was searching for, among other things, subject files and diaries related to the Braeburn Study and other clinical research trials as well as

communications regarding the Braeburn Study and other clinical research trials. In addition, SAMI ANWAR had an attorney representing him and present during the execution of the search warrant. The DEA confirmed with SAMI ANWAR and his attorney that the search warrant was being executed as part of a criminal investigation.

144. After the search warrant had been executed, the DEA provided SAMI ANWAR and his attorney with a written inventory of the items the DEA had seized, many of which SAMI ANWAR had observed being seized by the DEA. As reflected on the written inventory, the items seized by the DEA included, but were not limited to, all of the subject binders for the Braeburn Study, imaged copies of the electronic data stored on the Defendants' computers, the above referenced box labeled "B-Study" from the attic of the Defendants' business premises containing plastic bags labeled "No-Show," which held undistributed rescue medication, along with empty pill bottles that Defendants had falsely stated had been provided to subjects, and the above referenced plastic baggie from SAMI ANWAR's desk drawer containing 590 hydrocodone pills.

145. As of January 24, 2018, if not before, SAMI ANWAR knew that two individuals, then current employees of his, were cooperating with the DEA. Specifically, by the day of the DEA's execution of the search warrant at the Defendants' business premises, SAMI ANWAR had intercepted and reviewed text messages indicating that the two employees had been communicating with the DEA prior to the execution of the search warrant. As SAMI ANWAR knew, both employees had direct knowledge of the Conspiracy. This included, but was not limited to, direct knowledge of multiple clinical research trials, gained as study coordinators for SAMI ANWAR, including but not limited to the Braeburn Study,

and details of the manner in which the fraud had been and was at that time being perpetrated by the Conspiracy.

146. In fact, both before and after the execution of the search warrant, both then-current employees were cooperating with the DEA in its investigation of the Conspiracy and the Defendants' respective roles in it. At that time, both employees were providing incriminating information to the DEA regarding the Defendants' fraudulent activities on multiple clinical research trials. Those then current, now former, employees of SAMI ANWAR's are referred to herein as "J.B." and "H.E.," respectively.

147. On February 2, 2018, approximately one week after the execution of the search warrant, and approximately one week after SAMI ANWAR having obtained evidence of J.B.'s communication with the DEA, the Defendants' Human Resources Manager called the Richland Police Department and reported that stolen items, specifically a binder and prescription pills, had been found in J.B.'s vehicle.

148. Upon investigation of the allegations against J.B., the Richland Police Department investigating officer found evidence wholly inconsistent with the allegations. Further, when contacted at the scene by the investigating officer, J.B. promptly allowed a further search of J.B.'s vehicle, denied any wrongdoing, disclosed J .B.'s status as a cooperating witness with the DEA, and provided J.B.'s suspicion that SAMI ANWAR was attempting to frame J.B.. The Richland Police Department made no arrest based on the allegations against J.B. and did not refer any charges to any prosecuting authority.

149. Subsequently, J.B. received a letter from the Washington State Department of Health ("DOH") informing J.B. that the Medical Assistant Program within DOH had received a complaint against J.B.. The allegations in the complaint, which placed J.B.'s license to continue practicing as a Medical

Assistant in jeopardy, was based in part on being terminated by the Defendants for allegedly stealing medications.

150. As to H.E., starting on or around February 13, 2018, a few weeks after the execution of the first search warrant, a few weeks after SAMI ANWAR obtaining evidence that H.E. was communicating with the DEA, H.E.'s car tires began getting routinely slashed. This happened on six separate occasions over approximately four months on the following dates: February 13, 2018; March 5, 2018; March 26, 2018; April 26, 2018; June 1, 2018; and June 21, 2018. These tire-slashings occurred despite H.E.'s complaints to law enforcement advising of H.E.'s belief that SAMI ANWAR was behind the incidents, despite H.E.'s efforts to park in different locations and even, on one occasion, H.E.'s efforts to evade the tire-slashing by using another person's car.

151. By way of further example only, the same day of the execution of the search warrant, January 24, 2018, SAMI ANWAR, along with an employee of the Defendants, called a former employee who had been a study coordinator in the Braeburn Study, and who is referred to herein and above as "A.C.." During that call, SAMI ANWAR told A.C. that A.C. should change A.C.'s number as the DEA would try to contact A.C. Also during the call, SAMI ANWAR informed A.C. that SAMI ANWAR was going to tell DEA that the rescue medication in the Braeburn Study was dispensed to all of the subjects. SAMI ANWAR further informed A.C. that he, SAMI ANWAR, was going to blame a former employee of his, the medical provider J.H. referred to above, for the undistributed rescue medication found by the DEA during the execution of the search warrant. As provided above, J.H. was the former employee and medical provider that SAMI ANWAR had recently attempted to obtain false Washington State Department of Health

complaints from patients against including by use of force against one patient and A.C.'s family.

152. By way of further example only, in March of 2018, SAMI ANWAR told Dr. Doe, who was still employed by SAMI ANWAR and MID COLUMBIA RESEARCH at that time, not to meet with the DEA in Spokane, as had been scheduled. At that time, SAMI ANWAR reassured Dr. Doe that if the DEA took Dr. Doe's DEA Registration away he, SAMI ANWAR, would take care of Dr. Doe. SAMI ANWAR further told Dr. Doe that anything Dr. Doe told the DEA could be used in court and further that if the DEA had anything on Dr. Doe they, the DEA, would have already told Dr. Doe. Dr. Doe followed the instructions of SAMI ANWAR, who was still Dr. Doe's employer, and canceled Dr. Doe's meeting with the DEA at that time. It would be several more months before Dr. Doe would meet with the DEA and cooperate with the investigation.

153. In September of 2018, weeks after the DEA had executed a second search warrant on the Defendants' business premises, SAMI ANWAR went to A.C.'s new place of employment where he/she worked as a bank teller. At that time A.C. had ceased A.C.'s earlier cooperation with the DEA because of A.C.'s fear of what SAMI ANWAR might do to him/her. SAMI ANWAR approached A.C. at that time and asked A.C. if the DEA had contacted A.C.. When A.C. did not provide an answer to SAMI ANWAR's question SAMI ANWAR showed A.C. a note with the names of five persons SAMI ANWAR suspected of cooperating with the DEA. A.C. felt threatened and intimidated by SAMI ANWAR's unannounced, pretextual visit to A.C.'s work and by SAMI ANWAR's questions and statements regarding cooperation with the DEA.

154. By way of further example only, in March of 2018, weeks after the execution of the first DEA search warrant, a long-time employee of the

Defendant's resigned because the employee did not want to continue to work where fraud was being committed. As SAMI ANWAR knew, the employee had worked on multiple clinical research trials for SAMI ANWAR in multiple capacities and therefore had detailed knowledge of the Conspiracy. This former employee is referred to herein as "D.G."

155. After D.G. resigned SAMI ANWAR appeared unannounced at D.G.'s home and entered uninvited. At that time, SAMI ANWAR threated D.G. Specifically, SAMI ANWAR told D.G. that if he, SAMI ANWAR, were to go to jail then so would D.G. SAMI ANWAR went on to threaten D.G. by stating that if he, SAMI ANWAR, went to jail he would ensure that D.G.'s spouse, who is not a U.S. citizen, would be deported. SAMI ANWAR also threatened D.G. that if he, SAMI ANWAR, went to jail then D.G.'s family would be broken. SAMI ANWAR made these threatening comments in front of D.G.'s minor child.

156. D.G. felt threatened by SAMI ANWAR and accordingly moved with D.G.'s family to a new residence with an undisclosed address in the hopes of avoiding SAMI ANWAR.

157. Subsequently, after the DEA executed its second search warrant on the Defendants' business premises on July 30, 2018, SAMI ANWAR located and went, uninvited, to D.G.'s new residence at the undisclosed address. At that time, SAMI ANWAR made additional threatening statements to D.G.

158. On November 7, 2018, this Grand Jury returned an Indictment in this cause and on November 8, 2018, SAMI ANWAR was arrested and placed in custody. On November 16, 2018, while SAMI AWAR was still in custody, D.G. received the following text message from a current employee of SAMI ANWAR's:

> I talked to Dr. [SAMI ANWAR] today they denied his release. And I talked with both him and [SAMI ANWAR's wife] and they wanted me to ask it you would come help

> me with preparing the appeal. He wants [SAMI ANWAR's sister] and I too get all this shit from Braeburn. He told me you know more about then [sic] us and for me to ask you and [D.G.'s spouse] for help. I told him I'd ask. It's cool if you don't want to I get it.

As SAMI ANWAR knew, the Braeburn Study had been terminated over a year before, D.G. had previously declined to come back to D.G.'s former employer to provide assistance and in fact had changed D.G.'s residence out of the fear of SAMI ANWAR and accordingly the text from his current employee to D.G. at his direction served no purpose except to further threaten and intimidate D.G.. In fact, D.G. was placed in additional fear of SAMI ANWAR as a result notwithstanding that he remained in custody.

COUNT 2
CONSPIRACY TO COMMIT MAIL FRAUD

159. The Grand Jury re-alleges and incorporates by reference paragraphs 1 through 158 of the Superseding Indictment as if fully set forth herein. Further, the allegations in all other counts in the Superseding Indictment are re-alleged and incorporated into this count as if fully set forth herein.

160. Beginning on a date unknown to the Grand Jury, but no later than on or about November 25, 2013, and continuing until at least on or about November 16, 2018, in the Eastern District of Washington, the Defendants SAMI ANWAR, MID COLUMBIA RESEARCH, ZAIN RESEARCH, and persons both known and unknown to the Grand Jury, did knowingly combine, conspire, and agree to commit certain offenses against the United States including the following offenses, to wit, knowingly devised and intended to devise a scheme and artifice to defraud Pfizer, ICON, Parexel, Braeburn, Medpace, CSM, other sponsors and CROs, and prospective sponsors and CROs, both known and unknown to the Grand Jury, and

to obtain payments from Pfizer, ICON, Parexel, Braeburn, Medpace, and other sponsors and prospective sponsors, both known and unknown to the Grand Jury, and hydrocodone and morphine from CSM, using interstate mails, the United States Postal Service, and private and commercial interstate carriers in order to execute and attempt to execute the said scheme and artifice to defraud in the ways, manners, and means described in paragraphs 46 through 158 of this Superseding Indictment and referred to herein as the Conspiracy, in violation of 18 U.S.C. §§ 1341, 1349.

161. For example, as part of the Conspiracy, the checks sent by Medpace, and funded by Braeburn, to MID COLUMBIA RESEARCH attention SAMI ANWAR, were sent using the interstate mails via the United States Postal Service and Federal Express, a private interstate commercial carrier. The checks sent by ICON, and funded by Pfizer, to ZAIN RESEARCH and SAMI ANWAR for the Cholesterol Study were sent using the interstate mails via the United States Postal Service. In addition, the drug shipments of hydrocodone and morphine from CSM received by MID COLUMBIA RESEARCH as part of the Conspiracy, were sent in the interstate mails via United Parcel Service (UPS) a private interstate commercial carrier.

COUNTS 3 - 25
WIRE FRAUD

162. The Grand Jury re-alleges and incorporates by reference paragraphs 1 through 161 of the Superseding Indictment as if fully set forth herein. Further, the allegations in all other counts in the Superseding Indictment are re-alleged and incorporated into this count as if fully set forth herein.

163. On or about each of the dates set forth below, in the Eastern District of Washington, the Defendants SAMI ANWAR, MID COLUMBIA RESEARCH, and ZAIN RESEARCH, and persons both known and unknown to the Grand Jury,

for the purpose of executing the Conspiracy described above and to obtain money from Braeburn and Medpace, and attempting to do so, did knowingly and with intent to defraud, based on materially false and fraudulent representations, omissions, pretenses, and promises, transmit and cause to be transmitted by means of wire communication in interstate commerce the signals and sounds described below for each count, each transmission constituting a separate count:

Count	Date of Wire	Description of Wire
3	On or about December 9, 2016	Email from an employee of SAMI ANWAR with initials H.E. to a Medpace Clinical Research Associate with initials M.K., with subject line "RE: Braeburn HS-16-555/ PI Contact Number, providing SAMI ANWAR's cellular telephone number and falsely stating that the number was for Dr. Doe's cellular telephone, and transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio.
4.	On or about July 19, 2017	IRT entry, transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio, for Subject 068-014 for Site 068 of the Braeburn Study falsely representing that one syringe of CAM 2038 was dispensed to that subject on July 19, 2017.

5	On or about July 26, 2017	EDC entry for Subject 068-014 in Braeburn Study HS-16-555 on Form (EGYN) Any ECG Test Results, with a false entry of "YES" for "Was a 12-lead ECG performed?" and transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio.
6	On or about July 26, 2017	EDC entry for Subject 068-014 in Braeburn Study HS-16-555 on Form (PEYN_ISE) Any Injection Site Exam, with a false entry of "YES" for "Was Injection Site Exam Performed?" and transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio.
7	On or about July 28, 2017	EDC entry for Subject 068-030 in Braeburn Study HS-16-555 on Form (IEYN) Any Inclusion Criteria Not Met, with a false entry of "YES" and transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio.
8	On or about August 14, 2017	IRT entry, transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio, for Subject 068-027 for Site 068 of the Braeburn Study falsely representing that one syringe of CAM 2038 was dispensed to that subject on August 14, 2017.

9	On or about August 15, 2017	IRT entry, transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio, for Subject 068-024 for Site 068 of the Braeburn Study falsely representing that 42 tablets of Hydrocodone were dispensed to that subject on August 15, 2017.
10	On or about August 15, 2017	IRT entry, transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio, for Subject 068-022 for Site 068 of the Braeburn Study falsely representing that one syringe of CAM 2038 was dispensed to that subject on August 15, 2017
11	On or about August 22, 2017	EDC entry for Subject 068-022 in Braeburn Study HS-16-555 on Form (IEYN) Any Inclusion Criteria Not Met, with a false entry of "YES" for "Did the subject meet all eligibility criteria?" and transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio.
12	On or about August 22, 2017	EDC entry for Subject 068-024 in Braeburn Study HS-16-555 on Form (IEYN) Any Inclusion Criteria Not Met, with a false entry of "YES" for "Did the subject meet all eligibility criteria?" and transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio.

13	On or about August 24, 2017	EDC entry for Subject 068-027 in Braeburn Study HS-16-555 on Form (IEYN) Any Inclusion Criteria Not Met, with a false entry of "YES" for "Did the subject meet all eligibility criteria?" and transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio.
14	On or about August 29, 2017	EDC entry for Subject 068-014 in Braeburn Study HS-16-555 on Form (Injection Site Exam) CURRENT INJECTION SITE, A, with a false entry of the date of injection as "14/Aug/2017," a false entry of the injection site type as "CURRENT INJECTION SITE," a false entry of the location of the injection as "A," and transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio.
15	On or about August 29, 2017	EDC entry for Subject 068-027 in Braeburn Study HS-16-555 on Form (LB_CNTRL) Laboratory Test Reults- Central Processing, with a false entry of "YES" for "Was the blood sample collected?" a false entry of "YES" for "Was the urine sample collected?" and transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio.

16	On or about August 30, 2017	IRT entry, transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio, for Subject 068-028 for Site 068 of the Braeburn Study falsely representing that 28 tablets of Hydrocodone were dispensed to that subject on August 30, 2017.
17	On or about September 1, 2017	EDC entry for Subject 068-022 in Braeburn Study HS-16-555 on Form (Injection Site Exam) CURRENT INJECTION SITE, A, with a false entry of the date of injection as "15/Aug/2017," a false entry of the injection site type as "CURRENT INJECTION SITE," a false entry of the location of the injection as "A," and transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio.
18	On or about September 1, 2017	EDC entry for Subject 068-028 in Braeburn Study HS-16-555 on Form (DA) Drug Accountability, with a false entry of "YES," for "Was study Rescue Medication Dispensed?" a false entry of the date dispensed as "30/Aug/2017," a false entry of "28" for "What is the amount dispensed? (in tablets)," and transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio.

19	On or about September 5, 2017	EDC entry for Subject 068-024 in Braeburn Study HS-16-555 on Form (DA) Drug Accountability, with a false entry of "YES," for "Was study Rescue Medication Dispensed?" a false entry of the date dispensed as "15/Aug/2017," a false entry of "42" for "What is the amount dispensed? (in tablets)," and transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio.
20	On or about September 13, 2017	IRT entry, transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio, for Subject 068-028 for Site 068 of the Braeburn Study falsely representing that 14 tablets of Hydrocodone were dispensed to that subject on September 13, 2017.
21	On or about September 14, 2017	EDC entry for Subject 068-028 in Braeburn Study HS-16-555 on Form (DA) Drug Accountability, with a false entry of "YES," for "Was study Rescue Medication Dispensed?" a false entry of the date dispensed as "13/Sep/2017," a false entry of "14" for "What is the amount dispensed? (in tablets)," and transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio.

22	On or about October 3, 2017	IRT entry, transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio, for Subject 068-024 for Site 068 of the Braeburn Study falsely representing that 14 tablets of Hydrocodone were dispensed to that subject on October 3, 2017.
23	On or about October 4, 2017	EDC entry for Subject 068-024 in Braeburn Study HS-16-555 on Form (DA) Drug Accountability, with a false entry of "YES," for "Was study Rescue Medication Dispensed?" a false entry of the date dispensed as "03/Oct/2017," a false entry of "14" for "What is the amount dispensed? (in tablets)," and transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio.
24	On or about October 9, 2017	EDC entry for Subject 068-014 in Braeburn Study HS-16-555 on Form (Date of Visit) 9/22/2017, with a false entry of "YES" for "Did the subject attend this visit?" and transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio.

25	On or about October 9, 2017	EDC entry for Subject 068-014 in Braeburn Study HS-16-555 on Form (VSYN_DOSE) Any Vital Signs-Pre/Post Test Dose, with a false entry of "YES" for "Were vital signs taken?" and transmitted via interstate wires from Richland, Washington to Cincinnati, Ohio.

All in violation of 18 U.S.C. § 1343.

COUNTS 26 - 40
MAIL FRAUD

164. The Grand Jury re-alleges and incorporates by reference paragraphs 1 through 163 of the Superseding Indictment as if fully set forth herein. Further, the allegations in all other counts in the Superseding Indictment are re-alleged and incorporated into this count as if fully set forth herein.

165. On or about each of the dates set forth below, in the Eastern District of Washington, the SAMI ANWAR, MID COLUMBIA RESEARCH, and ZAIN RESEARCH, and persons both known and unknown to the Grand Jury, for the purpose of executing the Conspiracy described above, and to obtain money from Braeburn and Medpace, and to obtain property, in the form of hydrocodone and morphine from CSM, and attempting to do so, did knowingly and with intent to defraud, cause to be delivered by the means specified below, the below mailings, each mailing constituting a separate count:

Count	Date of Mailing	Description of Mailing
26	On or about March 17, 2017	Check 68676, totaling $3,582.00, made out to "Mid Columbia Research, LLC" for Braeburn Study payment through January 2017, sent in the interstate mails via the United States Postal Service.
27	On or about April 13, 2017	Check 69161, totaling $9,639.00, made out to "Mid Columbia Research, LLC" for Braeburn Study payment through February 2017, sent in the interstate mails via the United States Postal Service.
28	On or about May 25, 2017	Check 69821, totaling $17,192.00, made out to "Mid Columbia Research, LLC" for Braeburn Study payment through March 2017, sent in the interstate mails via the United States Postal Service.
29	On or about June 8, 2017	Check 70067, totaling $21,666.00 made out to "Mid Columbia Research, LLC" for Braeburn Study payment through April 2017, sent in the interstate mails via the United States Postal Service.
30	On or about July 6, 2017	Check 70563, totaling $16,690.50 made out to "Mid Columbia Research, LLC" for Braeburn Study payment through

		May 2017, sent in the interstate mails via the United States Postal Service.
31	On or about August 14, 2017	Check 71010, totaling $36,702.00 made out to "Mid Columbia Research, LLC" for Braeburn Study payment through June 2017, sent in the interstate mails via the United States Postal Service.
32	On or about September 7, 2017	Check 71628, totaling $40,000.50, made out to "Mid Columbia Research, LLC" for Braeburn Study payment through July 2017, sent in the interstate mails via the United States Postal Service.
33	On or about October 13, 2017	Check 72068, totaling $66,691.50, made out to "Mid Columbia Research, LLC" for Braeburn Study payment through August 2017, sent in the interstate mails via the United States Postal Service.
34	On or about November 27, 2017	Check 72873, totaling $58,479.30, made out to "Mid Columbia Research, LLC" for Braeburn Study payment through September 2017, sent in the interstate mails via Federal Express, a private interstate commercial carrier.

35	On or about November 22, 2016	CSM Shipment Order number 60372-112216 containing hydrocodone and morphine rescue medication, in response to the DEA Form-222 submitted on or about November 15, 2016, sent in the interstate mails via United Parcel Service (UPS), a private interstate commercial carrier.
36	On or about June 1, 2017	CSM Shipment Order number 68268-053117 containing hydrocodone and morphine rescue medication, in response to the DEA Form-222 submitted on or about May 31, 2017, sent in the interstate mails via UPS, a private interstate commercial carrier.
37	On or about July 24, 2017	CSM Shipment Order number 70550-072117 containing hydrocodone and morphine rescue medication, in response to the DEA Form-222 submitted on or about July 19, 2017, sent in the interstate mails via UPS, a private interstate commercial carrier.

38	On or about August 23, 2017	CSM Shipment Order number 71738-082317 containing hydrocodone and morphine rescue medication, in response to the DEA Form-222 submitted on or about August 22, 2017, sent in the interstate mails via UPS, a private interstate commercial carrier.
39	On or about September 26, 2017	CSM Shipment Order number 72994-092617 containing hydrocodone and morphine rescue medication, in response to the DEA Form-222 submitted on or about September 11, 2017, sent in the interstate mails via UPS, a private interstate commercial carrier.
40	On or about September 28, 2017	CSM Shipment Order number 73085-092717 containing hydrocodone and morphine rescue medication, in response to the DEA Form-222 submitted on or about September 25, 2017, sent in the interstate mails via UPS, a private interstate commercial carrier.

All in violation of 18 U.S.C. § 1341.

COUNTS 41 - 46
FRAUDULENTLY OBTAINING
CONTROLLED SUBSTANCES

166. The Grand Jury re-alleges and incorporates by reference paragraphs 1 through 165 of the Superseding Indictment as if fully set forth herein. Further, the allegations in all other counts in the Superseding Indictment are re-alleged and incorporated into this count as if fully set forth herein.

167. On or about the dates below, in the Eastern District of Washington, the SAMI ANWAR, MID COLUMBIA RESEARCH, and ZAIN RESEARCH, and persons both known and unknown to the Grand Jury, knowingly and intentionally obtained and acquired morphine and hydrocodone, both Schedule II controlled substances, by misrepresentation, fraud, forgery, deception, and subterfuge, to wit, the Conspiracy, including, but not limited to, by submitting and causing to be submitted forged and fraudulent DEA-222 forms, purportedly signed by Dr. Doe and affixing Dr. Doe's DEA Registration Number, all without his knowledge or authorization, and through MID COLUMBIA RESEARCH to Clinical Supplies Management Inc., (CSM) of Fargo, North Dakota, fraudulently ordering and obtaining amounts and quantities of the Schedule II controlled substances listed below, each instance constituting a separate count:

Count	Order Date	Date Obtained	Controlled Substances Obtained
41	On or about November 15, 2016	On or about November 23, 2016	15 packages of 100 count bottles of hydrocodone/acetaminophen 5 mg/325 mg tablets with lot or serial numbers HD16216_0697 to HD16216_0711

			3 packages of 100 count bottles of morphine sulfate 15 mg tablets with lot or serial numbers 659418C_141 to 659418C_143
42	On or about May 31, 2017	On or about June 2, 2017	15 packages of 100 count bottles of hydrocodone/acetaminophen 5 mg/325 mg tablets with lot or serial numbers HD16216_1245 to HD16216_1259 1 package of 100 count bottle of morphine sulfate 15 mg tablets with lot or serial number 659418C_236
43	On or about July 19, 2017	On or about July 25, 2017	11 packages of 100 count bottles of hydrocodone/acetaminophen 5 mg/325 mg tablets with lot or serial numbers HD16216_1531 to HD16216_1541 1 package of 100 count bottle of morphine sulfate 15 mg tablets with lot or serial number 659418C_274

44	On or about August 22, 2017	On or about August 24, 2017	11 packages of 100 count bottles of hydrocodone/acetaminophen 5 mg/325 mg tablets with lot or serial numbers HD16216_1694 to HD16216_1704 1 package of 100 count bottle of morphine sulfate 15 mg tablets with lot or serial number 659418C_292
45	On or about September 11, 2017	On or about September 27, 2017	11 packages of 100 count bottles of hydrocodone/acetaminophen 5 mg/325 mg tablets with lot or serial numbers HD16216_1826 to HD16216_1836
46	On or about September 25, 2017	On or about September 29, 2017	4 packages of 100 count bottles of hydrocodone/acetaminophen 5 mg/325 mg tablets with lot or serial numbers HD16216_1894 to HD16216_1897 1 package of 100 count bottle of morphine sulfate 15 mg tablets with lot or serial number 764031A_410

All in violation of 21 U.S.C. § 843(a)(3).

COUNT 47
FURNINSHING FALSE OR FRAUDULENT
MATERIAL INFORMATION

168. The Grand Jury re-alleges and incorporates by reference paragraphs 1 through 167 of the Superseding Indictment as if fully set forth herein. Further, the allegations in all other counts in the Superseding Indictment are re-alleged and incorporated into this count as if fully set forth herein.

169. On or about May 12, 2017, in the Eastern District of Washington, the Defendants SAMI ANWAR, MID COLUMBIA RESEARCH, and ZAIN RESEARCH, and persons both known and unknown to the Grand Jury, knowingly and intentionally furnished false and fraudulent material information in a DEA Form 225, an application for registration under the Controlled Substances Act required to be made, kept, and filed under 21 U.S.C. § 823(b) and 21 CFR § 1301, to wit: forging Dr. Doe's signature and affixing Dr. Doe's DEA Registration Number, all without his knowledge or authorization, and supplying other false and fraudulent information in Defendants' application to the DEA for the GHB Study, in order to obtain authorization to possess and distribute GHB, a Schedule I controlled substance. All in violation of 21 U.S.C. § 843(a)(4)(A).

NOTICE OF FORFEITURE ALLEGATIONS

The allegations contained in this Superseding Indictment are hereby re-alleged and incorporated herein by this reference for the purpose of alleging forfeiture.

Pursuant to 18 U.S.C. § 981(a)(1)(C) and 28 U.S.C. § 2461(c), upon conviction of an offense(s) in violation of 18 U.S.C. §§ 1343, 1349, Wire Fraud; and/or 18 U.S.C. §§ 1341, 1349, Mail Fraud, as alleged in this Superseding Indictment, the Defendants, SAMI ANWAR, MID COLUMBIA RESEARCH, LLC, and ZAIN RESEARCH, LLC, shall forfeit to the United States of America

any property, real or personal, which constitutes or is derived from proceeds traceable to the offense(s). The property sought for forfeiture includes, but is not limited to, the following:

Money Judgment

A sum of money of at least $411,513.89 in United States currency, representing the amount of proceeds obtained from the wire fraud and/or mail fraud violations.

If any of the property described above, as the result of any act or omission of Defendants:

(a) cannot be located upon the exercise of due diligence;

(b) has been transferred or sold to, or deposited with, a third party;

(c) has been placed beyond the jurisdiction of the court;

(d) has been substantially diminished in value; or

(e) has been commingled with other property which cannot be divided without difficulty,

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the United States shall be entitled to forfeiture of substitute property pursuant to 21 U.S.C. § 853(p), as incorporated by 18 U.S.C. § 981(a)(1)(C) and 28 U.S.C. § 2461(c).

DATED this 5 day of February, 2019.

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For

Joseph H. Harrington
United States Attorney

Daniel Hugo Fruchter
Assistant United States Attorney

Tyler H.L. Tornabene
Assistant United States Attorney